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GENERIC PESTICIDE REGISTRATION

HEARING

BEFORE THE

SUBCOMMITTEE ON ENERGY AND AGRICULTURE

OF THE

COMMITTEE ON SMALL BUSINESS
HOUSE OF REPRESENTATIVES

ONE HUNDREDTH CONGRESS

FIRST SESSION

WASHINGTON, DC, JUNE 24, 1987

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GENERIC PESTICIDE REGISTRATION

WEDNESDAY, JUNE 24, 1987

House of Representatives,
Subcommittee on Energy and Agriculture,
Committee on Small Business,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:06 a.m., in room 2359-A, Rayburn House Office Building, Hon. Charles Hatcher (chairman of the subcommittee) presiding.

Present: Chairman Hatcher; Representatives Ray, Bilbray, Martinez, Dreier, Combest, and Gallegly.

Mr. Hatcher. Good morning.

We will get started with the hearing.

I want to thank all of you for taking time to be with us this morning as we hold a hearing on what I consider to be an important issue.

I am Charles Hatcher and I chair this Subcommittee on Energy and Agriculture of the Small Business Committee.

This morning, we will be looking into the impact of H.R. 2569 on small agri-chemical companies, farmers, and consumers. I think this resolution is aptly titled the "Pesticide Price Competition Act of 1987," because competition is what this bill is all about and what sparked my interest in this subject.

H.R. 2569 would amend the Federal Insecticide, Fungicide, and Rodenticide Act, known as FIFRA, to establish generic pesticide registration after a product's 17-year patent expires.

I believe this legislation would result in more competition within the pesticide industry and, ultimately, lower prices for pesticides.

The bill is vitally important to many small agri-chemical companies throughout our country because it would facilitate their entrance into the marketplace by allowing generic pesticide production.

I would like for some of the witnesses, if you will, to comment on what some say is a corollary between human drugs and pesticides in treatment regarding patent term and generic entry.

This morning, we are going to hear from a number of people, some of whom, from looking at the list, will be for the bill and some of whom will be against the bill. I am looking forward to learning from you today. I am sure that what you have to say will be well received by the committee and will be the beginning of our consideration of this resolution.

Once again, I would like to thank everyone for participating in the hearing today, and at this time, I would like to welcome back to the subcommittee and back to Congress, Richard Ray, who has been away a few weeks. Welcome back, Richard. Good to have you here.

Congressman Dreier will be here momentarily, and at that time, we will allow him to make any opening remarks he desires.

At this time, I would like to call on you, Richard, for any opening remarks you might like to make.

[Chairman Hatcher's prepared statement and attachment may be found in the appendix.]

Mr. RAY. Thank you, Mr. Chairman.

Do you want me to proceed with any testimony I have right now or wait for Mr. Dreier?

Mr. HATCHER. I think you can make any remarks you like now, including your testimony.

Mr. RAY. All right, sir.

Mr. Chairman, I want to commend you for holding this hearing today. I am delighted to be here this morning as a member of the subcommittee, and also as a supporter and cosponsor of H.R. 2569, the Pesticide Price Competition Act. I believe that this hearing will serve as an excellent forum for examining this issue and will draw attention to this important legislation.

I commend you for your leadership on this issue, which is very much needed, and very much appreciated by myself, my colleagues on the subcommittee, and by the members of the industry.

As most of you know, before coming to Washington, I was a small businessman for 23 years with most of that time being spent in the pest control industry. For this reason, I am very cognizant of the effect that the current FIFRA regulations have on the ability of small businesses to enter the pesticide production industry. This lack of access leads to less competition and ultimately higher prices for consumers.

This is an important issue, and it must be and needs to be addressed.

Mr. Chairman, I am especially pleased that you have invited Mr. Virgil Young from Fort Valley, GA, a friend of mine whom I have known all of my life, to testify at this hearing.

We grew up on nearby farms in Fort Valley, GA. We have worked closely together over the years, much of it having been in the chemical industry. Virgil has worked in the pesticide industry for 37 years and is currently the president of Tenkoz, a consulting business that advises businesses about the purchase of pesticides.

I value his insight and advice and am very pleased that he is able to be here this morning. I believe that my colleagues on this subcommittee will benefit from his testimony here today.

Once again, Mr. Chairman, I want to thank you for holding what promises to be an important and informative hearing on this important issue, and I thank you for giving me the opportunity to say a few words this morning on behalf of H.R. 2569.

Mr. HATCHER. Thank you very much, Richard.

At this time, I would like to call on Congressman Dreier for any comments he would like to make.

Mr. DREIER. Thank you very much, Mr. Chairman.

I am sorry to be tardy. I left our office corridor—we are right next to each other—at about 6 minutes of 10 and got into a very crowded elevator. So, I apologize for being late.

I would like to compliment you on your choice of topics for this, the first hearing of what I think is a very important subcommittee, our newly created Subcommittee on Energy and Agriculture.

Although I do not have any major agricultural interests within my specific congressional district, not many people are aware of the fact that the largest industry in my State of California is not tourism, people going to Disneyland, or the defense industry, but, in fact, it is the agriculture industry.

In addition, I have a keen interest in the farming sector of the economy. All of my constituents are like everyone else, consumers of farm products and the farm economy. As we have seen in recent years, it is a very integral part of our overall national economy.

I am very pleased to have the opportunity to serve with you on this subcommittee, and I look forward to working with you on issues relating to energy and agricultural policy and their impact on small business.

Regarding the issue at hand this morning, I would like to briefly express my support for the efforts to increase competition in the pesticide industry and subsequently lower the costs of pesticide products to the American farmer.

I am a cosponsor of H.R. 2569, the Pesticide Price Competition Act, because I believe congressional intent regarding reasonable compensation for the use of registered health and safety data by generic pesticide producers should be clarified. We need to do more to eliminate barriers to competition in our economy, but, at the same time, I believe it is only fair that businesses which invest millions of dollars in developing a product with no guarantee of a product market be fairly compensated by competitors who are seeking to copy their products.

I realize that we will be shedding more light on the issue this morning, but I hope we can go further and come to some consensus on what reasonable compensation should be.

I thank you very much again, Mr. Chairman, for calling this hearing and look forward to the witnesses' testimony.

Thank you.

Mr. HATCHER. Thank you, Mr. Dreier.

Next, I would like to call on Larry Combest for any comments he would like to make.

Mr. COMBEST. Mr. Chairman, thank you.

I thank you for the honor of serving with you on the Agriculture Committee and the opportunity during the consideration of the reauthorization of FIFRA during 1985 and 1986, of course, which did not get finished. I thought whenever I got off that subcommittee [DORFA], I was through with FIFRA, and here we are.

But, I do appreciate the fact you would hold these hearings. I think these hearings are very critical, certainly timely, and, as well this is an adequate location to have this hearing on small business because it does impact small businesses tremendously. It impacts the small businesses of agriculture and farming in west Texas and other areas.

I think we have the same interest here and that is to try to see exactly what we are getting ourselves into without compensation. It is a very hot issue, one that certainly is debated strongly on both sides. I think our interests are the same and those are that we continue to have an adequate product, which is safe, not only for farmers, but for the public as well; and that it impacts on farmers through their costs as well as on the general public and their food supply.

Certainly, we have trade implications that concerning compensation, impact very directly on how other foreign countries and foreign manufacturers can or cannot deal in this country. These concern: What they do to cost and pricing, of course; what it does to your own production here; and, certainly, and as equally important, what are the safety assurances that we must have to insure that pesticides are, No. 1, adequate to do the job and, No. 2, safe, both for the applicator as well as for the public.

So, I commend you for holding these hearings. I look forward to getting on with them, and with that, I suggest we do so.

Mr. HATCHER. Thank you, Mr. Combest.

The first witness on the schedule is Mr. Robert Fields. Is Mr. Fields here?

Mr. FIELDS. Yes, sir.

Mr. HATCHER. Mr. Fields is associate general counsel for FMC Corp. and will be testifying on behalf of the National Agricultural Chemical Association.

And who do you have with you, Mr. Fields?

Mr. FIELDS. Mr. Chairman, I have Harold Himmelman, an attorney with the law firm of Beveridge and Diamond in Washington, DC, with me this morning to help me answer some questions.

Mr. HATCHER. Mr. Fields, do you have a prepared statement?

Mr. FIELDS. Yes; I do, Mr. Chairman.

Mr. HATCHER. That statement will be made a part of the record without objection, and you are free to read it or to speak and proceed as you wish.

Mr. FIELDS. I would appreciate it if I could read it, Mr. Chairman. It is fairly short.

Mr. HATCHER. All right.

TESTIMONY OF MR. ROBERT J. FIELDS, ASSOCIATE GENERAL COUNSEL, FMC CORP., ON BEHALF OF NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION [NACA], ACCOMPANIED BY HAROLD HIMMELMAN, ATTORNEY, BEVERIDGE & DIAMOND, WASHINGTON, DC

Mr. FIELDS. Mr. Chairman, I am Robert Fields. I am associate general counsel for FMC Corp., a manufacturer of machinery and chemicals for industry, agriculture, and government. I am testifying today on behalf of the National Agricultural Chemical Association [NACA].

We believe the current system of data compensation has proven fair and equitable to all concerned and should be retained in its present form. We are, therefore, opposed to H.R. 2569.

Mr. Chairman, recognizing that we do have an honest difference of opinion over your proposal to eliminate the current data compensation provisions from the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA], we want to thank you for providing us the opportunity to testify before your committee.

Let me begin by focusing on what is at stake with this proposal, which goes to the heart of what is required to develop better, safer, and more cost-effective products.

First, current data requirements by EPA to register a chemical for commercial application are substantial and are increasing. Painstaking and expensive research is necessary to synthesize and develop the very few chemicals that possess the unique characteristics required of a successful pesticide, that is, the ability to selectively control pests without harming humans and the environment.

Only one of every 20,000 compounds screened for possible field use shows promise of becoming commercially viable. It typically costs a registrant company $15 million and takes up to 5 years simply to develop the extensive information required to support pesticide registration. These costs are borne by the registrant with no guarantee of commercial success.

In addition, the registrant companies must have the necessary scientific expertise available to develop the required supporting data. Innovation requires not only the synthesis of new compounds, but also a screening for biological and pesticidal activity, and a range of residue, metabolism, toxicology, and environmental fate studies.

Moreover, the costs directly attributable to registration are but a fraction of the development costs for a new product. The total investment to commercialize a new product typically runs into the tens of millions of dollars. EPA has estimated it can run from $20 to $70 million per product without any guarantee of commercial success.

Moreover, the elapsed time from initial discovery through long-term field studies to submission for first commercial registration averages 7 years. In sum, the process is risky, expensive and time consuming.

Eliminating the data compensation provisions of FIFRA not only eats away at the incentives to R&D, but also will add to our balance of trade deficit, will prove detrimental to the environment, and will prove costly in the long run to one of our most beleaguered small businesses, the American farmer.

Let me proceed to discuss each of these impacts of H.R. 2569 by first focusing on the small business aspect of this legislation.

You will hear this morning from those who will portray this issue as one of small versus big business; of the Davids—the small generic companies—versus the Goliaths—the large research companies—but this is not an accurate representation.

Small firms also play a significant role in developing new products. In total sales volume, the company I represent is much smaller than many of the me-too registrant companies. FMC's modest size in comparison to many generics is not untypical of other U.S. R&D companies which are decidedly smaller than the so-called small businesses which support this change in the current data compensation system.

The me-too companies, which support your amendment, Mr. Chairman, are not only often many times larger than domestic research and development companies, but, in many instances, represent convenient front firms for offshore agricultural chemical giants.

In short, it is inaccurate to characterize the me-too pesticide licensee as without the resources to generate the data required to register a product for sale or to compensate often smaller companies which have taken the risk and made the substantial research investment in hope of producing a safer, more cost-effective product.

Many me-too registrants are, in fact, large companies or are backed by large foreign suppliers. Indeed, as the agricultural chemicals industry has consolidated over the last several years, four of the world's top five firms are offshore companies. Some of these offshore firms do their own original research and provide jobs in the United States, but others devote substantial resources to finding ways to exploit the lucrative U.S. agricultural chemicals market. These offshore firms seek to enter the U.S. market at the expense of U.S. innovator companies, which are typically plowing back 10 percent or more of their sales into research to find the next more cost-effective product.

Second, Mr. Chairman, this bill has important trade implications. Congress is currently examining ways to assist other U.S. industries to regain their competitiveness in world markets. Many of these industries suffer at the expense of copy-cat foreign producers which imitate U.S. technological advances without spending money for product R&D.

These foreign producers are vitally interested in changing the existing data compensation system for agricultural chemicals. They have a proven record of acquiring, adapting and controlling U.S. technologies to the detriment of U.S. manufacturing jobs. They are prepared to do the same in agricultural chemicals at the expense of our balance of trade and U.S. jobs.

Elimination of data compensation will drive more agricultural chemicals business offshore and erode what is now a favorable balance of trade for this sector of our economy.

Third, we should not discount the environmental consequences which would result from elimination of data compensation. Each generation of agricultural chemicals provides farmers and the public with greater field effectiveness and overall environmental benefits. The R&D companies are committed to continued innovation which will lead to even greater environmental protection in the future.

By upholding the effective, current data compensation system, Congress provides an important incentive for these continuing advances in product development, which will mean more efficient food production with less pesticide use and greater environmental safety.

In short, it is research dollars that are making pesticides safer.

Finally, and perhaps most importantly for this committee, Mr. Chairman, you will hear this morning from those who will make claims that eliminating the data compensation system from FIFRA will benefit farmers, providing an annual $200 to $500 million cost savings.

These figures were developed by a $9 billion generic producer. They misrepresent, in our opinion, the real costs to farmers of eliminating the FIFRA data compensation system, that is, a corresponding reduction in R&D to find more cost-effective products.

Moreover, their figures are based on an extrapolation from only three products, the patents for which have expired. In fact, it is not unusual for agricultural chemical prices to fall as products get older and they are replaced by newer, more cost-effective products.

Let me emphasize, again, the real price farmers will pay if we eliminate data compensation, is the immediate reduction in the dollar and cents commitment of American R&D companies to research and a resulting slow-down in innovation to develop newer, safer products.

Minor crop growers will be among the first to suffer the reduction in R&D efforts as the development of new agrichemicals is inhibited, and as pests develop resistance to older products, farmer and consumer costs will increase due to crop loss and the need to use greater quantities of chemicals.

Most importantly, as with other U.S. industries, the American farmer will become increasingly captive to offshore agri-chemical producers who use American technology without having to bear any of the costs of health and safety research. Nor do many generic producers provide valuable infield service capabilities or application training, which are standard technical service capabilities of R&D companies.

In fact, it is marketplace competition from alternative pesticides which currently, and will continue, to lead to lower prices. A study done for EPA found an average of five competing herbicides and five insecticides available for use on each major crop reviewed. This competition will continue to have a beneficial cost impact on small farmers who, themselves, are struggling to maintain their competitiveness.

In sum, Mr. Chairman, the current data compensation system is not a road block to competition. It simply requires that all would-be manufacturers of a product be on an equal footing. We would ask, is it fair for generic companies, many of them larger than their R&D counterparts, to forego any up-front investment in R&D and obtain the immediate benefits of registration, that is, market access, without having borne any of the associated costs?

FIFRA already requires mandatory licensing. Now, the me-tooers want a free lunch. FIFRA's data compensation provision, indeed, allows a method for permitting me-too companies to gain immediate access to the data they seek. It further provides an arbitration process if negotiations between R&D companies and me-too registrants are not successful.

Moreover, it does not inhibit me-too companies from doing their own research. The system has worked to the benefit of U.S. jobs, the environment, and, most importantly, the American farmer.

We urge this committee to examine data compensation in light of these facts and for its true impact on small business.

Again, Mr. Chairman, we thank you for your consideration of our views.

Mr. Hatcher. Thank you, Mr. Fields.

I would like to ask you a couple of questions and then recognize members of the panel of the subcommittee for questions.

It seems to me that you have mentioned, essentially, two reasons why this legislation should not become law, and that is that it would inhibit research and ultimately harm the farmer rather than helping him by lowering prices; and, second, you have mentioned that many of them—I do not know if you used these words, but fly-by-night operators who do not have the ability to really service the industry—that some of them are offshore giants.

I assume you are not contending that all the folks who want to get into this business as generic producers fall into those categories?

Mr. FIELDS. That is correct, Mr. Chairman.

Let me address your first point. It is our firm belief that the greatest competition in the industry, and to the benefit of the farmer, comes from the production of new pesticides, the newer herbicides, the newer insecticides, which are used at a much lower per-acre rate, have better environmental controls, and have better human health factors.

It is that competition that we think is most critical and where my company, FMC, and the other producers spend their research and development dollars, and it is that incentive to come up with the next generation of pesticides that we are very concerned with.

On your second point, no; I am not implying that every single company that I am talking about is a front for an offshore producer.

Let me, if I may, just answer that by a long statement as to the characterization of the industry.

There are approximately 3,000 companies that formulate pesticide products and 90 of those companies, who also formulate, do produce generic compounds. There are approximately 24 to 30 companies worldwide who innovate new compounds.

So, you have got, basically, three tiers of chemical companies: The innovators, who develop the new compounds; the 90 or so companies, who basically formulate or do produce generic compounds; and 3,000 formulators, who, basically, purchase product from companies, such as FMC.

The 3,000 companies that purchase product from FMC to formulate do not have to pay data compensation at all, and that is a provision in FIFRA. So, what we are really talking about is a disagreement between the 90 companies and the 24 companies who do the development.

Mr. HATCHER. You do not contend that the passage of this legislation would prove costly to farmers in the short run, do you? Even your own statement, you say—let us assume for a moment that it would be largely offshore companies, for purposes of this question, who came into the market.

Would that not lower the cost of these products to the farmer, at least initially?

Mr. FIELDS. Perhaps, Mr. Chairman.

What I am concerned about is the continued commitment, for example, that my company has to the pesticides that we have innovated. We are continually required—Mr. Campt and Mr. Gray are here this morning from EPA and they can talk to data requirements—we are continually required by EPA because of updating data bases or problems which may arise in a compound's use, to spend millions of dollars. In fact, we are in Furadan, on avian toxicity, spending a lot of money right now on a compound which is not new to maintain this product for farmer use.

It is that kind of product stewardship, if you will, that we are very concerned with. The company that has basically R&D'd the compound, the father of the chemical, if you will, is the one who pays attention to it and the one who continues to spend research and development dollars on new studies, and we also make people available to the field to assist the farmer in using the chemical.

Mr. HATCHER. Are you familiar with the treatment of human drugs as far as generic registration, the generic producers?

Mr. FIELDS. Yes, Mr. Chairman; I am, and I was involved in the FIFRA hearings last year and helped work out a compromise, which I was hoping would pass, and Mr. Combest was on the Agriculture Committee and knows about the particular negotiations that went on last year.

The charge is that if the pharmaceutical industry allows generic production of chemicals after the patent is off, why does not the pesticide industry do the same thing, and the answer is, basically, that the pesticide industry and the pharmaceutical industry are not the same at all.

It costs approximately the same in R&D dollars to come up with a new pesticide as it does to come up with a new pharmaceutical, but I am told that on the average, the sales volume or the market for new pharmaceuticals is approximately 10 times the size of that for pesticides. Therefore, they have a much greater market and much greater revenues, and I am sure they would debate it, but I would state perhaps that they are almost able to give their data away because it is not as important to them as it is to us because of the difference in the size of the markets.

Mr. HATCHER. Thank you.

Mr. Dreier.

Mr. DREIER. Thank you very much, Mr. Chairman.

I would like to follow up on a couple of questions and say that, first of all, Mr. Fields, that FMC is one of the larger employers in my district. You may not be aware of it, but you have an arm called the sweeper division in Pomona, CA.

Mr. FIELDS. Yes, sir.

Mr. DREIER. And, so, with that in mind, I would like to welcome you here.

I would like to touch on some of the Environmental Protection Agency issues. First, I would like to ask about how long it takes for new pesticide registrations to be received?

Mr. FIELDS. From the day that we supply the data to the date of registration?

Mr. DREIER. Right.

[Pause.]

Mr. FIELDS. Within the agency, approximately 2 to 3 years. It takes approximately 5 to 7 years to develop the data and get it approved. So, by the time we would find an efficacious molecule, if you will, to the time we get a registration from EPA, it can take anywhere between 5 to 7 years.

Mr. DREIER. Do you think that there is any way that that amount of time could be reduced, and could have a salutary impact on the whole issue?

Mr. FIELDS. I probably am not the best one to answer that particular question, but because of the field trials and the animal testing which has to be done and the review period necessary for the EPA to do what has to be done, I would suspect no.

I mean, the long-term carcinogenicity studies, which are done on rats or mice, take 2 to 3 years, and, frankly, I do not know how you could shorten the time frame of those studies or the field studies or perhaps EPA's review. If you could, you are probably talking about months and not years.

Mr. **Dreier**. In your testimony, you talked about the competition factor, and I wonder, what types of barriers are there to direct competition with U.S. firms?

Mr. **Fields**. Are you talking about within the R&D firms?

Mr. **Dreier**. Right. Within the R&D firms, which you had mentioned.

Mr. **Fields**. Well, I guess the answer is there are no barriers to competition, except what the Patent Office gives you in the form of a patent for a new molecule.

We are all competing hotly with each other to develop the next generation of herbicides or the next generation of insecticides, and it is a race to come up with the most effective compound for the farmer, the safest pesticide, and take that molecule to the U.S. Patent Office to get a patent on it.

But, of course, that is a legal monopoly, if you will, granted by the United States laws. The competition that our companies are involved in is a fierce competition for survival of each company and the industry to look for tomorrow's pesticide, and it is costing upwards of $20 million per compound that we bring to the field.

Mr. **Dreier**. You responded to Chairman Hatcher's question about generic drugs by saying that there is a difference between the drug industry and the pesticide industry.

What similarities are there?

Mr. **Fields**. I guess the similarities, from what I understand are the cost of developing the new compounds, the field work that must be done either on a field for pesticides or animal or human trials for drugs, the care with which one must develop the chemical to make sure that it is both efficacious and safe for the farmer, for food consumption, or for the consumer, if it is a drug.

There are many, many differences, though. Obviously, pharmaceutical products can be used year around. Pesticides cannot. Pesticides, like pharmaceuticals, are basically designed for a specific use. I guess that is a similarity.

But, again, the tremendous dissimilarity from our particular standpoint, obviously, is the tremendous variance in the size of the markets between pharmaceuticals and pesticides.

Mr. **Dreier**. I guess the reason I asked that, Mr. Fields, is just the tremendous success that we have seen in the area of generic drugs and R&D, and many made the exact same prognostication which you have, and then we see, since 1981, a doubling of R&D, and that is why I just wonder if we cannot in some way take advantage——

Mr. **Fields**. Mr. Dreier, I will add that when the generic application or generic registration of pesticides did take place, at the same time the industry did get patent term restoration. There was a quid pro quo for that.

Mr. **Dreier**. Thank you very much, Mr. Chairman.

Mr. HATCHER. Before recognizing the next member, I would like to just follow up briefly on that.

Could we compromise on that? Give you patent term restoration in this legislation? Would that be acceptable?

Mr. FIELDS. Mr. Chairman, I guess I would like to answer that question by discussing the compromise that the industry worked out last year with what was then the Pesticide Producers Association.

There was patent term restoration in the bill last year for up to, I believe, 5 years of regulatory time lost in marketing a compound. The problem that the pesticide producers had last year was certainty. They were concerned about going into an arbitration process and, by the way, we would not be here today if it were not for just one case that there had been complaints about, and that was the *Stauffer PPG* case. There was only one case that anybody was complaining about.

So, the system really has not had a lot of time to work itself out, and the Congress did grapple with this particular issue in 1978. It went to arbitration.

What we tried to do last year was a compromise, which Mr. Combest knows did pass the House and the Senate and kept bouncing back and forth and is now called the bounce package and which was that the PPA-type company could go to arbitration before they applied for registration and if they did not like the award of the arbiters, they could walk away from that arbitration.

The arbitration would be binding against my company, FMC, for example, but a PPA company could walk away from it. Now, we thought that was a rather fair compromise reached last year to give them certainty, so to speak, in the marketplace.

Now, I will add one other statement. In the *Stauffer PPG* case, in our view, perhaps the arbiters did take size of the companies into consideration. Stauffer, which supposedly won the case, was a much smaller company than PPG.

We have only had the experience, in my view, of one really solid arbitration case, and we tried to urge the Congress last year not to throw out impartial arbitration based on one case, and I would make the same plea to you today not to do that. What is in the bounce package, which passed the Agriculture Committee last year, and I think is before it again this year, is nonbinding arbitration, nonbinding for the pesticide producers but binding on the R&D company. We think that is a very fair compromise.

Mr. HATCHER. Well, what if you got this legislation plus patent term restoration? Would not research continue at least at its current level and perhaps increase? Would that not give you time to recoup your investment and to make a reasonable profit?

Mr. FIELDS. There is one problem that comes to mind immediately with that, Mr. Chairman. There are compounds presently on the market which have very, very valuable and expensive data bases, which would not get patent term restoration.

It is those compounds that we do not have an answer for. They never will get patent term restoration. They only had 11 years of a patent because of the 7 years it takes to get registration. They are off patent now and their data bases are worth many, many millions of dollars, and my company is in that situation exactly today.

You could not legally, in my view, because we discussed this last year, restore the patent to those compounds and then the data would all of a sudden be free under your scenarios.

So, I would have a problem with that.

Mr. HATCHER. Would that be the sole reason that you would have a problem? Would that be the sole reason you would have a problem with my proposition?

Mr. FIELDS. The data call-ins would also present a particular problem. We are continually required to update our data base and we would have to spend a lot of money to answer the data call-in from the Environmental Protection Agency, pay for it ourselves, and that data would also be free.

Those are two that would come to the top of my head right now, Mr. Chairman.

Mr. HATCHER. Thank you.

Mr. Ray, you have some questions?

Mr. RAY. Mr. Fields, thank you for your testimony. You have done a very fine job with it.

Mr. FIELDS. Thank you, sir.

Mr. RAY. You have held FMC out to be a modest organization, but with its divisions, it is a rather large company, is it not?

Mr. FIELDS. In the aggregate, with machinery, governmental services, and chemicals, yes, sir.

Mr. RAY. You are in the defense business?

Mr. FIELDS. Yes, sir; we are.

Mr. RAY. Building a fighting vehicle?

Mr. FIELDS. Yes, sir.

Mr. RAY. In excess of $1 million per copy, and all of this sprang from the fact that FMC was a small company at one time, building food, machinery, plus manufacturing chemicals.

Mr. FIELDS. That is correct.

Mr. RAY. Well, I just thought we ought to set the record straight, that FMC is really not, in its total, a small operation at all.

Mr. FIELDS. No; we are a $3.5 billion company all total, sir, but our agricultural chemical division is much, much smaller, in the several hundred million dollar range, but I would add this, that corporate management today looks at each individual business under the corporate umbrella to see whether it is producing, and they are treated really as individual segments, although they are part of a large corporation. That is correct.

Mr. RAY. Well, I just wanted to clear the record. There are some who might not know that—to hold it out as a modest corporation might indicate that it was actually smaller than some very small companies. I think FMC has access through these various divisions to additional funds in case they get into serious situations and so forth.

Well, I just wanted to set the record straight in that respect. Thank you.

Mr. HATCHER. Mr. Martinez.

Mr. MARTINEZ. Just one question.

In your testimony, you touched on several different costs. The costs of research and development and the cost of promoting your product, $20 to $70 million, depending on the product.

I understand that the idea of the 17-year patent is to protect your rights during that period of time. I would assume that the 17 year period was established to give you a chance to amortize your costs for the research, development, and marketing of the product.

Are you saying that 17 years is not long enough?

Mr. FIELDS. Well, that happens to also be true on some average pesticides, and the average $40 million a year pesticide, sir, takes about 20 years to recapture your capital investments.

But I like to look at it as, really, two different things. The patent protecting the discovery of the molecule. The registration data, which EPA requires, is something quite different than that. It is not the market or the invention. This is the data that we have to supply at additional great cost to get a registration.

So, although, when the patent is over, any company is free to come into the market and, by the way, they can come into the market by simply writing a letter to the Environmental Protection Agency offering to pay us in arbitration or through negotiations for the data. They can get in very quickly, or they can produce their own data.

But we think the data, and I would submit to you that the data is very different than what the patent protects, which is the invention of the molecule.

Mr. MARTINEZ. Let me ask you one more question. God knows the farmers are struggling. We hear about farmers losing their farms all the time. Of course, the cost of running a farm is escalating like anything else.

I guess the idea is that given time, these products should not put the farmers out of business in order to protect themselves, the public, and the environment.

You indicated in testimony that the cost would be increased after a period of time.

Mr. FIELDS. Exactly.

Mr. MARTINEZ. The farmer, like a good businessperson, wants to make sure that he or she is using the best available product because it is going to give the greatest return. The better the product, the better the return.

Mr. FIELDS. Yes, sir.

Mr. MARTINEZ. In that sense then, the idea of this legislation, I imagine, is to reduce costs. I am new to this issue, so I am making certain assumptions. If I am wrong, correct me.

But if you are operating on that assumption, you want to see farmers succeed as much as you want to see your own company succeed. Businesses that supply other businesses have a responsibility. There is, you might say, a fiduciary relationship there and you work to improve their productivity as best you can.

When I had a small business, I had distributors who passed their savings on to me. They knew that any time they could pass on savings to me, I was going to be that much more successful in business and continue to buy from them.

What I am trying to say is that there is a reciprocal responsibility. At a point in time, say after 20 years, these products can be produced at a lower cost by a generic system. If you still did not feel you could reduce your costs of production and you still had to consider the cost of research and development and marketing, then maybe somebody else could reduce costs. Because they were not starting from ground zero, they would not have to make that big investment you had initially.

Could not something be worked out?

Mr. **Fields**. Well, as I said earlier, I think the Congress did work something out and that was impartial binding arbitration, and I would think that if the system were allowed to work, Mr. Congressman, we would find out that the system that the Congress designed in 1978 is not unreasonable.

Again, we are here today because of one decision, which some companies object to, and I would submit that based on further trials and binding arbitration, that they might be very satisfied with the results.

This was a case between two large companies, as has been characterized here today, and I would submit to you, if you examine the decision of the arbiters and the Federal court that reviewed the case, that the decision was perfectly appropriate.

The compensation awards that may be given to a data generator, my company, for example, are not going to be that large relative to markets that these companies want to go into that will have an adverse impact on the farmer.

I would suggest to you that pesticide costs per acre are not that great. The data compensation award, which may be granted to my company against the pesticide producer, are not going to have an adverse impact on his ability to sell, perhaps, a less-expensive product to the farmer, and, again, it is our contention and we are committed to the farmer that the best benefit to the farmer can be for my company to go out and spend money at great risk to develop the next generation of pesticides which will reduce the per-acre costs for a farmer.

Mr. **Martinez**. Thank you, Mr. Chairman.

Mr. **Fields**. Thank you.

Mr. **Martinez**. I have no further questions.

Mr. **Hatcher**. All right. Mr. Bilbray.

Mr. **Bilbray**. Yes; I have been going through this list of the cost per acre.

Now, you say it takes 20 years, more or less, on your R&D program to be paid off, your capital investment into a particular——

Mr. **Fields**. On an average $40 million a year pesticide. That is the figure I have, sir.

Mr. **Bilbray**. Now, does your price ever go down for your pesticides? In other words, as you get to a certain point, and you keep continuing to develop a market, and you get more and more of the market, and the time goes by, and you are recovering your costs, do we ever reach some sort of a curve where we start driving the price down?

Mr. **Fields**. Sir, I wish I could answer the question, but I do not know the history of the prices of FMC's agricultural chemicals.

Mr. **Bilbray**. Once you recover your initial cost, then I think the majority of the committee feels that some sort of savings should be passed on to the farmers. It should not continue just to be a profit. We do not want to take away your product or your research and give it to some third party.

I would like to see the companies help this curve start going down. On the other hand, if the companies will not, then, at a certain point when you have made this development, you have recovered your costs, you have made your profits, some of that profit sharing should go on to the people who are the end users of that product.

Mr. FIELDS. I do not disagree with any of that, Mr. Congressman.

One of the problems we have is that we are continually required to update our data base that is on file with the EPA and particular compounds that FMC has, and I know that the requirements to update that data base are getting very substantial.

So, it is not just, at least in the case of one of my compounds, a one-time expense to submit data to the Environmental Protection Agency. It is an ongoing responsibility which continually costs us a lot of money.

I would further state that if a generic producer wants to compete with us in a market that we are in and the patent is off, they ought to take the case to arbitration if, in fact, we cannot agree on a price, and whatever the award is, I am sure they will be able to afford to pay it because what they do is they only pick out the compounds which, in my view, are the lucrative big-hit compounds. They do not go for the little ones that do not have a great market. They have already identified the market, which is a market that we established through our marketing techniques, and so forth.

So, they are not gambling on picking a compound which has a low annual sales figure. They are picking those compounds which have already identified a market and have a niche, and they know they are going to make money. They know they are probably going to make a lot of money.

The initial investment for them is probably quite small compared to the fact that they can be in the market immediately with no risk. We had none of those assurances when we came in.

Mr. BILBRAY. I would like to see if you could supply this committee with some data on products that, for instance, are 10 or 15 years on the market? The cost of that product, when it started, what it cost to develop, what your profits have been, also what the price of that product is to the ultimate consumer today.

Thank you.

Mr. HATCHER. Mr. Fields, it seems to me that a very key and critical point in your testimony is your position that binding arbitration is working and it is fair. If that were a generally-shared opinion, we would not be here today, and I would not have introduced this legislation.

It is very inhibiting. I do not know if you are aware of that. You mentioned there has only been one case, the *PPG Stauffer*, and the fact is that is an important case and one that scared the hell out of a lot of generic producers.

But, there are also a lot of people, some of them in this room, who have been through and who are going through arbitration. They find it very costly, very time-consuming, and almost never-ending.

So, I would submit to you that, perhaps, the most fundamental reason we are here today is that arbitration, binding arbitration, is not a viable option; it is not working; it is too costly, too cumbersome, too time-consuming, too inhibiting, too threatening, and, actually, we are not anywhere approaching what happened in the *Stauffer* case to happen to most generic producers. They would be not just wondering whether to go through another binding arbitration and try to sell some other pesticides, but wondering when to close their doors and go into some other business or into bankruptcy.

Any other questions?

Mr. DREIER. We have Mr. Combest, Mr. Chairman, a very important person.

Mr. HATCHER. Mr. Combest.

Mr. COMBEST. Thank you for coming back to me, Mr. Chairman.

Mr. Fields, last year, in the consideration of FIFRA, there was a very delicate balance that was reached. I guess one of the most delicate balances in any legislative package that has ever been reached in regard to various issues and concerns in that there was not a compromise reached on the data compensation issue.

Are you still willing to live with the compromise that was reached last year?

Mr. FIELDS. Yes, sir. We are.

Mr. COMBEST. And the patent provisions of this bill contain a compromise repeal of the so-called *Bolar* decision, which was agreed to last year by all parties. Do you still support that?

Mr. FIELDS. Yes, sir. We do.

Mr. COMBEST. In answer to a question posed by Congressman Dreier, I need to make sure that I have these figures as I thought you had asked them. My question to you was asked only to see if you could give me an average cost and time involved in a development of a new chemical from when you began to conceive of the idea of the need.

If I understood you correctly, you said it took between 5 and 7 years?

Mr. FIELDS. From the discovery of the molecule to registration from EPA, that is approximately correct.

Mr. COMBEST. To the point where it is on the market?

Mr. FIELDS. Yes, sir.

Mr. COMBEST. At a cost of?

Mr. FIELDS. We have some information I can get you on that, but I believe it is 5 to 7 years.

Mr. COMBEST. At a cost of?

Mr. FIELDS. $20 million.

Mr. COMBEST. That is what I thought you said.

One of the things that you mentioned in your testimony concerns us, because I hate for this to be, and do not want this to be, from a competition standpoint, from the standpoint of the benefit to the agriculture consumer, and certainly to the environment, and those things, a big versus small company issue.

Discuss with me just a little bit, if you would, how that also involves foreign trade issues. Is it the foreign producers versus the American producers—not the farmers themselves, but the producers of chemicals? Has foreign versus domestic come into play relative to the data compensation issue?

Mr. FIELDS. I will give you some examples without giving you names, but large foreign producers can set up or go into business with small formulators, some on the east coast, some on the west coast.

The small office of one of these formulators takes one of my companies to arbitration as between our two companies, but the critical point is that they are getting their supply of whatever the generic chemical is from a giant offshore company. Some of these are many, many billion dollar companies.

There is one company in Japan that is fairly well known. It is about a $9 billion company that is very capable of producing generic compounds. There are some in Israel.

Mr. COMBEST. As the gentleman had earlier mentioned, Mr. Ray, let us put it on the same terms, if we can.

That $9 billion company includes products other than chemicals?

Mr. FIELDS. No; this is all chemicals.

Mr. COMBEST. This $9 billion company produces strictly chemicals. We are thinking of a different company.

Mr. FIELDS. Excuse me. They may have other products. Excuse me.

Mr. COMBEST. That is their primary business.

Mr. FIELDS. They are in chemicals. They are also in machinery, I believe.

Mr. COMBEST. OK.

Mr. FIELDS. They basically form a partnership with some of the smaller companies in the United States. It is our view that a company of that size, if I am able to afford those costs, certainly they are, too, and what happens is they go into partnership with very small distributors in the United States, who take a larger company to arbitration, and it has been a small company and a large company, but what you have to do sometimes is peel back the pages and look to see who is behind the small U.S. representative and sometimes you will find that it is a very large offshore producer, who, in many cases, is not engaged in research and development at all, but is engaged in, as I said in my testimony, copy-catting things, and it is not only chemicals; it is electronics and other things.

They take what we make and compete with us.

Mr. COMBEST. In the area of chemicals, are there not significantly different requirements on a foreign company's development, and in a foreign country, of a pesticide or herbicide with regards to safety standards, environmental concerns in the plant?

Obviously, we have a difference in labor standards and those things.

Mr. FIELDS. Yes, sir.

Mr. COMBEST. Puts you into a pretty unfair competition standpoint.

Mr. FIELDS. We do have a difficult time, if you will, competing with some companies in some countries because of the higher cost of doing business in this country, from both an OSHA standpoint and an environmental protection standpoint. That is correct.

Mr. COMBEST. I think any data which this subcommittee could gather and get from you in regards to all of these hundreds of millions of dollars that *x* large company that develops a product may receive over a period of its life, and of its patent, would be important.

But, what I would like to see us do in this development, and I do not want to get to the point to where regardless of whether it is a farming operation or a business or whatever they thrive on, an economic benefit. Certainly, your company and others have got to make money. The smaller companies that we are discussing as well have got to make money.

I think many times we look in terms of the large dollars that turn over relative to a specific product and do not consider the amount of time, the cost of development—again the $20 million average cost that goes into development—the advertising and the other things which go into it.

Certainly, they cost more in other countries. Products, which are manufactured in this country, cost more in other countries than sometimes they do here, and we do not want to create a fair or unfair competition standpoint for the farmers, and, yet, I think it is also very important, given the environmental concerns, that we have these products.

I want us to be very careful as we consider this so that what we do not do is take away any of the benefit of a company to try to develop a new pesticide and herbicide, and as we look at the concern over environmental issues, particularly the technology today of detecting even smaller and smaller parts per million or billion, or whatever it is that we are testing for, that we are going to continually have to come up with new products that meet the standards to keep the environment clean and at the same time do good for that agricultural crop as it must.

Any of those that you can share, that are not trade secrets, at some point with this subcommittee, I would appreciate your sending. I do not want to know what your profit margin is. I do not think that is fair for us to do so, but I think it is also important that we look at what costs go into that product in marketing and everything else of it and anything like that that you would feel comfortable making public, I would appreciate.

Mr. FIELDS. I will make a submission to the committee. Thank you very much.

Mr. COMBEST. Thank you, Mr. Chairman.

Mr. HATCHER. Mr. Dreier, you have another question?

Mr. DREIER. Thank you very much, Mr. Chairman.

I would just like to follow up on one of the items that Congressman Combest had raised, and am I correct in assuming that the life, the 17-year life of the patent begins at the end of your period of 5 to 7 years?

Mr. FIELDS. No, sir; actually, it begins the day one of our scientists in Princeton, NJ, finds a molecule that he thinks may work and calls up our Philadelphia office and gets a patent attorney to file a patent application with the United States Patent Office. That is when the 17-year clock starts ticking, whenever that patent application is filed or is approved.

Mr. DREIER. So, conceivably then, it could be 10 years after the product is finally——

Mr. FIELDS. Basically, Mr. Dreier, the most we ever get out of a patent, I believe, is 11 years of patent protection. That is from the date of registration, when we can sell, to the end of the 17 years.

So, we do not, and have never gotten 17-year patent protection on a pesticide.

Mr. DREIER. OK, Mr. Fields. So, 5 to 7 years to develop it.

What is the total amount of time or the average amount of time that it takes to recoup the costs?

Mr. FIELDS. The only figure I have is that on an average $40 million-a-year compound, and, of course, some are higher and some are lower, it is approximately 20 years.

Mr. DREIER. About 20 years to recoup the cost?

Mr. FIELDS. On that compound.

Mr. DREIER. And the maximum life span of the patent is 11 years?

Mr. FIELDS. Yes, sir; now, of course we are also funding, and as I stated in my testimony, it takes us approximately 20,000 screenings of molecules to come up with one efficacious molecule.

So, some of our victories are paying for many of our failures. It is just a long and tedious process to come up with a compound that will work on a bug or a weed and will also pass Environmental Protection Agency scrutiny.

Mr. DREIER. Now, you talk about that 11-year period as a maximum. What is the trend? Is it increasing, decreasing, and what factors are there involved which are impacting either an increase or a decrease?

Mr. FIELDS. Costs are increasing. As far as the time period is concerned, I engaged in discussion with one of the gentlemen this morning—I forget which one—as to whether that 5- to 7-year time frame could be shortened, and I guess my answer was I do not think so.

Mr. DREIER. But that would——

Mr. FIELDS. I am sorry. I do not think so. It is because of the amount of time it takes to conduct the testing, the 2-year animal test is obviously a 2-year test, and then you have to do the autopsy, and study all the slides, and apply to EPA.

Maybe there is a way to shorten that timeframe somewhat, but I doubt if it would be significant. Obviously, if the requirements for data were to change, the timeframe could be shortened, but I am not sure that is a particularly good idea.

Mr. DREIER. Very well. Thank you very much for the testimony.

Thank you, Mr. Chairman. I will carry your regards to the people at the sweeper division in Pomona.

Mr. FIELDS. Thank you.

Mr. HATCHER. Are there any other questions of Mr. Fields?

[No response.]

Mr. HATCHER. If not, again, I would like to thank you for appearing before the subcommittee today and for your testimony.

Mr. FIELDS. Thank you very much, Mr. Chairman. I appreciate it.

Mr. HATCHER. At this time, I would like to call the next panel: Dr. Warren Stickle, executive director, Chemical Producers & Distributors Association; Mr. Rusty Griffin, president of Griffin Corp., Valdosta, GA; Mr. Virgil Young, president, Tenkoz, Inc., Fort Valley, GA; Mr. Robert Shockey, president, chairman, and chief executive officer, Champman Chemical Co., Memphis, TN.

Virgil, how do you pronounce your company's name?

Mr. YOUNG. Tenkoz, long o.

Mr. HATCHER. Tenkoz.

Dr. Stickle, do members of this particular panel have any preference as to which order they would like to proceed?

Dr. STICKLE. Yes, Mr. Chairman; I would like to say a few introductory words, if I might, and then ask Mr. Virgil Young if he would chat about some of his concerns, and then Rusty Griffin, and then Bob Shockey, and then for a couple of concluding remarks from myself, if that is possible.

Mr. HATCHER. That is fine.

You may proceed.

TESTIMONY OF WARREN E. STICKLE, EXECUTIVE DIRECTOR, CHEMICAL PRODUCERS & DISTRIBUTORS ASSOCIATION

Dr. STICKLE. Mr. Chairman, my name is Warren Stickle. I am the executive director of the Chemical Producers & Distributors Association.

We thank you for the opportunity to discuss some of the problems facing small businesses in the pesticide industry, especially the need to create more competition in the industry.

The Chemical Producers & Distributors Association is a voluntary, nonprofit membership association consisting of about 50 companies engaged in the manufacture, formulation, distribution and sale of products used on food, feed, and fiber crops, and for lawn and garden care.

We are primarily composed of small- to medium-sized businesses, and I would add most of which are in the process of selling products under $20 million in total sales for the year. These are small businesses engaged in the formulation, manufacture, and distribution of some $2 billion worth of agricultural pesticides. A majority of our members rely upon the production of generic pesticides. Those products on which the patent has expired.

Our membership provides a much-needed service to the agricultural community in formulating and distributing those chemical tools necessary to allow all of us to enjoy an abundance of agricultural products at a fair and competitive price.

Today, Mr. Chairman, I am accompanied by Mr. Robert Shockey, chairman of the board of Drexel Chemical Co., Memphis, TN, and president of the Chemical Producers & Distributors Association; Mr. Virgil Young, president, Tenkoz, Fort Valley, GA; and Mr. Rusty Griffin, president of Griffin Corp., Valdosta, GA.

We respectfully request that two additional statements be included as part of the official hearing record, and they include Mr. Jimmy Whatley, director, corporate research and development, the Griffin Corp., Valdosta, GA, and Mr. George Miller, vice president of TransChem Industries in Secaucus, NJ.

[Dr. Stickle's, Mr. Whatley's, and Mr. Miller's prepared statements may be found in the appendix.]

Mr. HATCHER. We will proceed with Mr. Young.

TESTIMONY OF VIRGIL YOUNG, PRESIDENT, TENKOZ, INC., FORT VALLEY, GA

Mr. YOUNG. Mr. Chairman, my name is Virgil Young. I am president of Tenkoz, Fort Valley, GA.

Tenkoz is owned by 11 formulator-distributor companies across the country, from Yuma, AZ, to Severn, NC. Tenkoz functions as a purchasing consultant for these small businesses who have a combined $300 million share of the ag chemical market. We employ some 650 people in some 20 States. Some of our companies are members of CPDA. Others are members of NACA.

Mr. Chairman, I would like to comment on three areas, data compensation, the need to repeal the *Bolar-Roche* decision, and the need for generic registration.

Data compensation. I believe that it is possible to stimulate greater competition in the pesticide industry if we can make it easier for small businesses, formulators, and distributors to enter the pesticide market. By changing the current data compensation provisions of FIFRA, we can achieve this goal.

When a company decides to enter a pesticide market after the expiration of the patent, it must be able to determine all of its potential costs in order to make a sound business decision. It can define the manufacturing process, the raw material costs, the cost of plant construction, the general overhead, and potential market.

While these items are sufficient in most businesses, there is one important element missing for a pesticide product—data compensation.

Small businesses and generic manufacturers are reluctant to attempt to enter markets when their potential data compensation costs will exceed their profits for many years. We believe that a decision, such as the *Stauffer PPG* decision, is totally outside the intent of Congress when it passed the requirements for reasonable compensation in 1972 or when the statute was amended in 1975 and 1978.

We believe the intent of this section was to allow a company which relied upon data submitted to the agency by another registrant to share the cost of development of the data and not to reward the original registrant for being the first to register the pesticide product.

We contend that such reward is the purpose of the patent laws and not FIFRA.

The need to repeal the *Bolar-Roche* decision. Current patent law allows the recipient of a pesticide patent an exclusive life of 17 years. Basic supplier companies have requested legislative changes to this law by asking that up to 5 additional years of patent life be added to the pesticide product.

The intent of the legislation is to restore lost patent life resulting from the lengthy regulatory review period needed to obtain EPA approval. While the product is being reviewed, it cannot be marketed.

In addition to the anticompetitive nature of the present system of determining data compensation, a recent decision by the U.S. Court of Appeals has brought into question the practice of developing data necessary to support the registration of an identical pesticide product prior to the expiration of a patent.

On April 23, 1984, the U.S. Court of Appeals for the Federal Circuit handed down a decision in *Roche Products* v. *Bolar Pharmaceutical,* ruling that the use of a patented product by a second party to develop data for the purpose of obtaining an earlier market entry following the expiration of a patent was a violation of the use provisions of the law.

The court held that while there was an exemption for the use of a product for scientific purposes, the exemption did not apply when the information gained was for commercial purposes. This decision prohibits the manufacture of a generic pesticide from developing any data which would be necessary for the registration of one product prior to the expiration of its patent.

This court decision effectively adds a period of up to 7 years to the term of a patent. In addition to the proposed 5-year extension, totaling a patent life of 29 years, if the bill should become law. This is shown in the following scenario. I will not read it.

In section 202 of the Drug Price Competition and Patent Term Restoration Act of 1984, the provisions were included to overrule the *Bolar-Roche* decision. Essentially, those provisions stated that it would not be an act of infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

If a product is to receive patent extension, as originally proposed by H.R. 2482 and S. 2792, 99th Congress, or as proposed in H.R. 1345, introduced by Congressmen Frederick Boucher and Michael DeWine, there should be a full repeal of the *Bolar-Roche* decision.

These legislative vehicles do not, however, contain a full repeal, but only a limited repeal for just 2 years. Such a limited repeal provides little benefit to generic manufacturers, especially if the testing and EPA review takes 5 to 7 years, leaving us with a 3- to 5-year deficiency.

In addition, the *Bolar-Roche* decision does not allow the generic manufacturer to submit his test results for EPA review prior to the expiration of the patent. Congress wisely created the generic pharmaceutical industry following patent term restoration and we feel that such a move within the pesticide industry would benefit all users.

We at CPDA believe that a generic manufacturer in the pesticide industry should be on equal footing with the drug manufacturers and do the testing and file an application for registration before the expiration of a patent, as long as there is a prohibition against marketing before the patent expires.

These de facto circumstances created by *Bolar-Roche* clearly prohibit market entry, deny small businesses access to the marketplace, and deprive farmers and consumers of lower priced pesticides.

Genera registration. We support H.R. 2569, the Pesticide Price Competition Act of 1987, introduced by Congressmen Charles Hatcher and Richard Ray. This legislation is patterned after the generic drug legislation that was enacted in 1984.

We think it is unfair to us and the farmer when we are kept out of the market after patent expiration. Paying for data after the patent expires is unfair to us. If one can prove to the EPA that its technical chemical is the same chemistry as the one registered and supported with data, it should be registered.

Let us take a moment to consider data costs. The data cost was paid for by the patent holder of the chemical, which lowered his tax obligation on the profits made. So, the taxpayers have paid for that.

Pricing of the product has included profits to offset all the restructure and development expenses. Who is the consumer in this case? None other than our farmers. In the early life of the product, the farmer paid the data costs. When the patent has expired, they want any would-be competitor to pay it again. If they do pay it, who will pay them back for the expense? The farmer.

Why should he pay again? In fact, the patent holders want the data compensation based on a multiple of the actual cost. They do not deserve to collect for the data two or three times while our farmers struggle. They do not really want the money for the data; they want to see businesses like ours and others give up the ship, and that is what will happen without drastic changes.

The small businessman can provide a quality product to the farmer at a lower cost. Large companies know and fear this fact. Dollars for the data cost is really not what they want. A protected market position that provides continuing high profit opportunities at the expense of the farmer is what they want.

As contained in H.R. 2569, generic registration would assist small business, formulators, and manufacturers in entering the marketplace after the expiration of the patent, breathe a new competitive spirit into the pesticide industry, and put us on a par with generic drug industry. But, most importantly, Mr. Chairman, it would lower pesticide costs for our farmers, ranchers, users and consumers.

I thank you for the opportunity to appear here today and be happy to answer any questions the subcommittee may have.

[Mr. Young's prepared statement may be found in the appendix.]

Mr. HATCHER. Thank you, Mr. Young.

I would like to proceed and hear from the other panelists and then we will open it for questions.

Let me remind all of you that your complete written statement will be made a part of the record without objection, and you are welcome to give the entire testimony, or any portion of it, or proceed as you will.

The next panelist we will recognize is Rusty Griffin from Valdosta.

Welcome, Rusty.

TESTIMONY OF RUSTY GRIFFIN, PRESIDENT, GRIFFIN CORP., VALDOSTA, GA

Mr. GRIFFIN. Thank you, Mr. Chairman.

Gentlemen, my name is Rusty Griffin. I am president of Griffin Corp., a privately held agricultural chemical company, with less than $75 million in sales this past year—substantially less than that.

I appreciate the opportunity to appear before you today and hope that I can be of some assistance to you in this matter.

First, I would like to say that I support H.R. 2569, the Pesticide Price Competition Act of 1987. It is a bill which supports the free enterprise system upon which this great country was built. It will help small business. It will help the American farmer reduce his costs, and, in turn, enable him to be more competitive in selling his products, agricultural products, through exports.

As you gentlemen are aware, exports of agricultural farm products make up a great deal of our balance of trade, make up a great deal of our favorable balance of trade in that particular sector.

This is a time of change for the agricultural chemical industry, much as for such other industries as trucking, banking, airlines, and pharmaceuticals. The industry is maturing and changing to a less protected environment. In many respects, it is becoming more commodity-oriented than patent-protected.

Those companies whose patents are expiring are seeking to maintain protections from competition—most notably, the encouragement of complex and expensive regulatory and data compensation processes, and this is a key point.

The way FIFRA currently works, it is extraordinarily hard for a small business to introduce a generic pesticide after patents expire. It is possible, but not easy, and certainly not practical on a wide scale.

For this reason, I think it is fully appropriate for Congress to put the pesticide industry on the same level playing field as the pharmaceutical industry was put a couple of years ago.

All may be fair in love and war, but the American farmer and the American people are victimized by the current situation. Over the last year or two, several spinoffs and mergers have taken place in our industry. Most have occurred because the agricultural chemical divisions of major corporations, some of which are oil companies, have not been able to adjust to a maturing market and have been unable to manage R&D effectively.

Quite simply, for too many years, they have rested on their laurels, introducing few, if any, new products, and many have become very bureaucratic and inefficient. Now, their historic managements have anticipated generic competition and have sought to avoid paying the piper.

The examples of these companies are: Velsicol of Northwest Industries, which has recently sold out; SDS of Diamond Shamrock—Shell has recently sold their U.S. division to DuPont; Stauffer, previously of Cheseborough-Ponds, and more recently of ICI. None of these companies have introduced major new products in recent years.

Management and other similar divisions lacking innovation have chosen not to sell out, but to milk their cash-cows. They have sought to impose the greatest possible barriers to competition.

High data compensation demands are a notable example of these barriers.

Even the handful of well-managed firms, which are introducing new innovative compounds, seek as many barriers to entry as they can. They, too, want to milk the older products as long as they can, and, in turn, milk the American farmer and the American consumer as well.

Earlier this month, I resigned from the board of directors of the National Agricultural Chemicals Association [NACA]. The reason was that the NACA Board passed a resolution which, in essence, stated that NACA planned to represent the views of the 10 or 15 biggies, as I call them—most of which are companies that are not

U.S. based, I might add—on those legislative and regulatory matters as to which a broader membership consensus could not be obtained. This decision, in my opinion, signaled a further major effort by the big companies to obtain even more barriers to small producers and distributors.

Perhaps most important to this committee and to Congress, this decision revealed that you may no longer look to NACA for advice on the views of our industry. NACA no longer speaks for our industry, but only for the dozen or so big international basic companies.

I have referred earlier in my statement to the anticompetitive misuse of the data compensation system. As you know, under current law, the process of binding arbitration allows original data submitters to receive compensation for their original toxicological and similar data, but, because the current law provides no clear and concise compensation standard, and because it discourages arbitrators from rejecting clearly extravagant claims earlier in the arbitration process, it is a very expensive and cumbersome process.

Our company is currently in the midst of an arbitration with DuPont in which they are demanding in excess of $7 million from us. This comes in connection with a product that they have been selling for some 25 years and have had 16 years of effective patent protection and the resultant monopoly profits.

We estimate that our legal and expert witness fees and related costs in this case will total between $400,000 and $500,000. We are also incurring massive demands on our own internal time which, when costed out, I am confident, will double the amount of the direct expense mentioned above.

In addition, DuPont has been successful in extending the proceedings from an initial estimate of 2½ or 3 weeks to now a projected 8 or 9 weeks. I honestly believe that they are happy to watch us bleed during this process.

Several hundred thousand dollars may be peanuts to DuPont, but is the heart of our overall earnings capability.

If they are successful in achieving their demands, our company's survival may be at stake. In short, the arbitration system is no where near as straight forward or efficient as one would hope. It can readily be manipulated to the disadvantage of new market entrants.

If H.R. 2569 is passed, it will eliminate this system. This is a laudable goal.

Our company is a small, entrepreneurial pesticide producer in the United States. We also export to some 40 foreign countries outside the United States. We are trying to do our part in the balance of trade problem. We are also a company that believes that research and development is the life blood of our country. We ask that Congress also take steps to encourage R&D in our country. However, the proper way to do this is not to discourage competition through an expensive and cumbersome arbitration procedure, but to take the same route as the pharmaceutical industry: to eliminate data compensation and establish realistic patent term restoration [PTR], which allows companies not to be burdened with a shortened patent life because of the delays required to get a pesticide through the regulatory process.

This approach will give the American consumer and the American farmer the benefit of lower chemical prices and help us be more competitive in our ability to export our products, our farm products in the future, and it is also a way that it will reward those companies which are well managed and successful in pesticide research.

It, thus, will provide greater incentives for more research, and it will eliminate the current anticompetitive manipulation of the arbitration system.

Gentlemen, I appreciate very much the opportunity to speak before you today. I appreciate your attention, and I would be delighted to answer any questions, either now, or after our other panelists speak.

Mr. HATCHER. Thank you. Now, we will hear from Robert Shockey.

TESTIMONY OF ROBERT D. SHOCKEY, CHAIRMAN OF THE BOARD, DREXEL CHEMICAL CO., MEMPHIS, TN, AND PRESIDENT, CHEMICAL PRODUCERS & DISTRIBUTORS ASSOCIATION [CPDA]

Mr. SHOCKEY. Good morning, Mr. Chairman and members of the subcommittee.

I am Robert D. Shockey. I am chairman of the board of Drexel Chemical Co., Memphis, TN, and president of the Chemical Producers and Distributors Association.

I would like to take a few moments to discuss with you the importance of generic pesticide registration and the Pesticide Competition Act.

Earlier this month, Congressman Hatcher introduced H.R. 2569, the Pesticide Price Competition Act. Senators Nancy Kassebaum and Al Gore introduced an identical bill on the Senate side on March 13. Each of these bills is patterned after the generic drug legislation that was enacted in 1984.

H.R. 2569 and S. 746 would establish an abbreviated generic pesticide registration, stimulate competition in the pesticide industry, and lower the price of pesticides to farmers, ranchers, users and consumers.

The purpose of this legislation is to lower the farmer's cost of production by reducing the cost of pesticides that farmers buy each year and to reduce the cost of nonagricultural products that consumers buy in their grocery and hardware stores.

This measure could save farmers from $400 million to $500 million per year for at least the next 5 years on agricultural pesticides alone. Consumers could save additional millions of dollars on nonagricultural products.

H.R. 2569 and S. 746 would eliminate the data compensation provision of FIFRA after the manufacturer has recouped his research and development costs over the 17-year life of the patent. If patent term restoration legislation [H.R. 1345], granting up to an additional 5 years protection, is passed by the 100th Congress, manufacturers would then have 22 years to recoup their R&D costs. After these 17 or 22 years, H.R. 2569 provides for an abbreviated application for the registration of generic pesticides, similar to the generic drug industry.

One way to help the farmer address the increasing costs of production is to face the problems head on. By amending the pesticide legislation, the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA], it is clearly possible—even desirable—to increase competition in the pesticide industry, resulting in reduced pesticide prices and lowering the farmer's cost of production without costing the Government a penny.

Increased competition will reduce pesticide prices. Farmers across this country apply agricultural pesticides to their crops, and these costs are a significant percentage of their cash expense, which includes seed, fertilizer, chemicals, hired labor, et cetera, that farmers pay each year.

According to recent figures gathered by the Economic Indicators of the Farm Sector, Cost of Production for 1985, prepared by the United States Department of Agriculture, pesticides average between 10 and 35 percent of all cash variable expenses. For soybeans, farmers spend $17.47 per acre for chemicals, equaling 32.3 percent of the cost of production. For peanuts, farmers nationwide, spend about $80 per acre for agricultural chemicals, or about 30 percent of their cost of production. For cotton, farmers spend $45 per acre, or 21 percent of their cost of production for pesticides.

For sugar cane, it is $56, and for rice, it is about $27 per acre. For corn, it is about $18 per acre, or almost 9 percent of their cost of production. Farmers also apply significant amounts of pesticides for tobacco, burley—$70 and flue-cured—$94. For wheat, it is almost $3 per acre for agricultural chemicals.

In essence, farmers spend a considerable amount of their cash reserve on pesticides.

If we can encourage the development of generic pesticides, we can lower the price of pesticides that farmers buy and reduce the farmer's cost of production. It may be possible to reduce the price of pesticides by 10 to 20 percent or more. For those crops like peanuts, cotton, rice, sugar cane and tobacco, we might be able to save the farmer some $5 to $25 per acre in pesticide costs.

For large acreage crops, like corn, soybeans, and wheat, we might be able to save farmers almost $3.50, $3.50 and $0.60, respectively. Without doubt, however, we can help the farmer reduce the cost of production at a time when the cost of most items purchased by the farmer have been rising higher and higher.

During the 1970's, generic pesticides led to price declines for DDT, atrazine, maleic hydrazine, diuron and simizine, resulting in millions of dollars in savings for American farmers. Other products coming off patent also experienced a decline in prices during the 1970's. Diuron, Dupont, and Simizine, Ciba Geigy, showed significant reductions. Diuron dropped from $3.25 per pound to about $2.40 per pound, a drop of 85 cents per pound, or 26.2 percent. Simizine declined from $15–$16 per gallon to $9–$10 per gallon, a drop of about $6 per gallon or 40 percent.

Another pattern also emerged during the 1970's. In 1977 and 1978 the basic manufacturers argued that they needed additional protection and asked Congress to enact a 10-year exclusive use period followed by a 5-year period of compensation. In 1978, Congress passed legislation containing these provisions.

"It is curious," remarked Donald Baker of the Department of Justice, "that the asserted need for protection of the test data, 1977, became evident only when significant numbers of pesticide patents began to run out. We find the disincentive argument somewhat ingenious."

During the 1970's, two patterns emerged. First, prices declined after the expiration of the patent, thus benefitting the farmers and consumers. Second, the industry demand for protection occurred when patents were beginning to run out, and these 1970's patterns have continued well into the 1980's, as well.

Generic pesticides lead to price declines in the 1980's. During the 1980's some major agricultural products came off patent and generic producers, with great difficulty, entered the marketplace, significantly reducing the price for consumers and farmers.

The following chart clearly indicates that these three pesticide products, phostoxin, treflan and sutan, have dropped an average of 18.1 percent.

PRODUCT TRADE NAME AND YEAR ENTERED THE MARKET

	Phostoxin (1982)	Treflan (1985)	Sutan (1984)
Pregeneric prices	[1] 30.20	[2] 28.50	[2] 19.89
Prices after generics entered the market, 1986	[1] 24.28	[2] 21.43	[2] 17.90

[1] Per kilogram.
[2] Per gallon.

During the 1980's we have witnessed a continued pattern of price reduction when pesticide products have come off patent, while other pesticide prices have increased. It is ironic that in the period between 1984 and 1987, the basic manufacturers have begun another major effort to protect their monopolistic control of the marketplace by requesting Congress to enact patent term extension, an effort to recover up to 5 years of time lost in the regulatory process at EPA.

It just happens that over the next 5 years, 1987–91, about 21 pesticides—some of the most widely used and most profitable—used by the American farmers will come off patent. These pesticides constitute about 45 percent of all pesticides used by farmers today.

As competition in any market develops, the price of product generally declines. Currently, a farmer in Central or South America is paying a lower price for his pesticide than an American farmer. As an example, insecticides being used on cotton are selling at $1 per pound overseas and $1.55 per pound in the United States. An insecticide for control of malarial mosquitos sells for $0.80 to $0.85 per pound overseas and $1.60 per pound in the United States.

Once a product comes off patent, its price can be expected to move closer to the world market price. The following list shows examples of U.S./foreign price differentials which exist now for several products.

The U.S. price is expected to move toward the more competitive foreign price. The following are the product comparisons.

Product	U.S. price	Foreign price
Malathion	[1] $1.55–1.65	[1] $0.82–0.95
Methyl Parathion	[1] 1.55	[1] 0.92–1.05
Carbaryl	[1] 2.55	[1] [3] 1.85
Treflan	[2] 26.00	[2] 16.00
Paraquat	[2] 32.00–36.00	[2] 13.00

[1] Per pound.
[2] Per gallon.
[3] Spain.

There are also products that, while still patented, nonetheless exhibit a price difference between U.S. and foreign markets, since the patent is not in force outside the United States, such as the product Round-Up produced by Monsanto. The United States price is $68 gal., and the foreign price is $40–$44 gal.

Without fair and equitable compensation in the pesticide industry, without legislation that reverses the *Bolar-Roche* decision, without the help of this subcommittee in obtaining generic registration for pesticides, our growers will always be at a disadvantage when they try to produce their own products.

We at the Chemical Producers and Distributors Association respectfully urge your support of H.R. 2569 and S.746, the Pesticide Price Competition Act, as a means to cut pesticide prices for farmers, ranchers, users, and consumers and reduce the cost of production for American farmers, without adding a single penny to our national debt or taking a dime out of the Federal Treasury. The generic pesticide registration will result in increased competition in the marketplace and within the pesticide industry resulting in lower prices on pesticides. In a period of escalating prices for essential farm items purchased by farmers and ranchers, is it now time to help reduce the basic cost of production and help revitalize rural America?

I would like to make one additional comment on Mr. Fields' testimony this morning. He made a comment that the re-registration will result in considerable testing and cost, and I believe that H.R. 2569 does not deal with re-registration costs, all of which is compensable under the FIFRA 3(c)(2)(b) provision.

Thank you, Mr. Chairman, I appreciate the opportunity to be here this morning and speak.

[Mr. Shockey's attachment to testimony may be found in the appendix.]

Mr. **HATCHER**. Thank you, Mr. Shockey.

Dr. Stickle?

Dr. **STICKLE**. I would like to take just a few additional moments to make some concluding comments, if I might.

Mr. Chairman, we strongly support H.R. 2569, the Pesticide Price Competition Act, that you and others have introduced. We commend you for your leadership on pesticide issues facing this Congress, especially the need to lower pesticide prices for farmers, ranchers, users, and consumers.

This legislation will make it easier for small businesses to enter the pesticide market and will make it easier for them to compete.

When the Congress granted patent term extension for drug products in 1984, the Congress also removed some of the barriers that made it difficult for generic drugs to enter the marketplace. Rather than unnecessarily duplicating the existing tests for registration of a particular drug, a generic manufacturer now need only to provide the FDA that his company can produce an identical chemical compound in order to begin marketing it.

We are proposing the same treatment for pesticides that come off of patent. It appears that the present administration also approves this approach. In a letter, dated March 10, 1986, Health and Human Services Secretary Otis Bowen wrote to Senator Strom Thurmond about restoring patent time loss due to Federal premarket requirements for veterinary drugs.

Quoting that letter, it says:

> In summary, we support patent restoration for veterinary drugs, but urge the Congress to add an additional provision that would enable manufacturers to obtain Federal premarket approval to market generic versions of these drugs without having to duplicate the potentially costly and time-consuming safety and effectiveness studies that are required of manufacturers. Without such a provision, there would appear to be no need for patent restoration since the current federal requirement for duplicative testing would continue to serve as an effective economic barrier to competition even after the expiration of the patent that would be restored by this legislation.

And continuing to quote that letter:

> Patent restoration would have little meaning, however, if federal regulatory barriers had the effect of preventing the marketing of virtually identical generic products after patents expire.
>
> We have concluded, Secretary Bowen pointed out, therefore, that both patent restoration and an abbreviated approval procedure ought to be included in the same legislation, so that they may be considered and hopefully enacted together.

Finally, Secretary Bowen pointed out:

> We continue to believe that it is good public policy to link the two concepts in order to foster research for new products and at the same time encourage competition and lower prices. In our view, it would be unfair to consumers as well as to the industry as a whole if one were enacted but not the other or if a substantial time lag occurred between the enactment of both.

Mr. Chairman, we respectfully request that the letter that Secretary Bowen sent to Senator Thurmond last year be included in the official record of the hearing.

Mr. HATCHER. Without objection, so ordered.

[The letter referred to may be found in the appendix as an attachment to Dr. Stickle's prepared statement.]

Dr. STICKLE. In conclusion, during each of the last three Congresses, the business issues of FIFRA, not the controversial environmental concerns, have generated sufficient conflict and dispute so as to frustrate the passage of needed pesticide amendments.

We would like to see these disputes over the business issues within FIFRA resolved to the satisfaction of the basic manufacturers, and small pesticide manufacturers, the generic pesticide producers, and the consumers, and farmers who depend on agricultural pesticides.

We believe that H.R. 2569 offers the best hope to resolve one of the most difficult and controversial issues of FIFRA, the generic pesticide registration and data compensation issue.

By adopting this legislation as part of a larger FIFRA amendment package, the Congress would inject a healthy dose of competition into the pesticide industry and give farmers and consumers a real break, and we can help farmers and consumers without costing the Treasury or the American people a single penny.

We applaud Congressman Hatcher and the other cosponsors of H.R. 2569 for their spirit of compromise and respectfully urge the subcommittee and the full committee to do all that it can to couple the Hatcher bill with future patent term restoration amendments. It is time to give the farmers a break. It is time to lower the cost the farmer pays for his commodities production-wise, and we can do this without taking any money out of the Federal treasury.

It is time to lower pesticide prices to consumers. It is time to give the pesticide industry a shot of deregulation. It is time to give small businesses an opportunity to more effectively compete in the pesticide marketplace, and it is time to work out a reasonable and workable compromise on the business issues of FIFRA.

We thank you very much for the time to come before your subcommittee and welcome any questions that you and the subcommittee would have.

Thank you very much.

Mr. HATCHER. Thank you, Dr. Stickle.

I would like to ask a couple of questions of Mr. Young.

Mr. Young, I am interested, as I indicated in my questioning of Mr. Fields, in whether there is a relationship and, if so, what relationship there is between the pharmaceutical industry and the pesticide industry, and is there some reason that they should be treated similarly in this matter.

Did you pay attention to Mr. Fields' comments on what he can see as the basic difference between the two industries?

Mr. YOUNG. Yes; sir. I heard it.

I would prefer that Rusty answer that question, if you would, sir.

Mr. HATCHER. All right.

Mr. GRIFFIN. I have heard that allegation before, Mr. Chairman. The pharmaceutical industry is somewhat larger than the pesticide industry. The pesticide industry in the United States is roughly a $5 billion industry.

The human pharmaceutical business is substantially larger than that, but the point is that both of those industries are made up of various segments. They are made up of this product and that product and this type of product and that type of product.

Each product has a certain potential or a certain volume. For instance, some of the pesticides that are sold in the United States today have a market potential of several hundred million dollars, some are actually achieving that sort of potential.

The same thing is true with the pharmaceutical industry. Many of the pharmaceuticals that are developed, however, have actually smaller potential than some of the pesticides.

So, what you are doing, and the way companies look at investing in research is they look at what can we develop and when you take those two different industries or take either one of those industries and break them down into the segments that they truly should be broken, you will find that investments should be evaluated in a very similar sort of manner as far as investments in R&D.

Mr. HATCHER. So, you would say there is a rather close relationship between how Government should treat the two industries?

Mr. GRIFFIN. Oh, very much so. Very much so.

Mr. HATCHER. Mr. Griffin, I know you have touched on it, but could you briefly describe for me your company's involvement in the generic pesticide industry, what products do you sell, or some of the key products, and how has this benefited farmers in Georgia, the Southeast, and throughout the country, if, in fact, it has?

Mr. GRIFFIN. We have, roughly, 12-14 products that make up, maybe, 85 percent of our volume. The majority of those products are products that many consider to be generic compounds.

Atrazine, for instance, is a compound that we currently sell. When we entered the Atrazine business some 7-8 years ago, the prices of those products were substantially higher than what they are today, which I think is clearly representing what competition can, in fact, do.

Most of the other compounds that we sell fall into that same sort of category. One that I mentioned is Linuron, which we are involved in arbitration with DuPont on right now, when I explained the expensive and cumbersome process that—and risky, I might add—process that currently exists according to current law.

Mr. HATCHER. I would like for you to expand on that a little bit. In the earlier testimony of Mr. Fields, it seemed to be his opinion that, or it was his opinion, if I heard correctly, that arbitration works, binding arbitration works, it is fair, it is a good way to go about handling things, and there is no reason to change it, and, after all, there has only been one decision and you need to let it run.

You mentioned or alluded to this earlier, but how really has this affected you individually, your company, and companies similarly situated? What effect does it have on you as a businessman?

Mr. GRIFFIN. Well, two or three different kinds of effect. One is, it discourages us from introducing new compounds because of the risk associated with it. There are several compounds whose patents have expired that we think we should get into. Some of those products we think we can improve, and actually reduce the farmers' costs through technological innovations as well as through just general competitive situation, but we have chosen not to introduce those products because the risk associated with data compensation provision as it exists today, not only the risk but also just the total cost.

I am talking about, literally, many, many hundreds of thousands of dollars to deal with these sort of things during the arbitration process, and it is just a risk we cannot afford, and it is a cost that we cannot afford. So, it impacts our decision to introduce new compounds.

Mr. HATCHER. Apart from the inhibiting factor that is in your deciding whether to go into a particular product, do you feel that you are putting the entire assets of your company and yourself up, like rolling everything you have got on the roll of the dice each time?

Mr. GRIFFIN. No doubt about it, and I think what is taking place now with the DuPont arbitration, as we refer to it, where they are asking for in excess of $7 million, if they are successful in their request, the future and viability of our company will certainly be in jeopardy.

Mr. HATCHER. Mr. Dreier.

Mr. DREIER. Thank you very much, Mr. Chairman.

I, first, would like to extend a welcome to my friend, Dr. Stickle, and thank you all very much for your very fine and interesting testimony.

It is fascinating to see the disparity which has taken place between the first two panels, Mr. Chairman. We have a little conflict, it seems, and I would like to try and shed some light on a few of those questions that have been raised by both of you.

First of all, one of the lines which came out of Mr. Fields' testimony is that generic manufacturers in this country are, and I am quoting this, "front firms" for offshore agricultural chemical giants, and I wonder if any of you would like to respond to that.

Mr. SHOCKEY. He did not name them. We do not know who they are, and, so, we do not—it is difficult to respond. I do not believe that that is the——

Mr. DREIER. Tennessee and Valdosta are not front operations for huge chemical giants?

Mr. GRIFFIN. I can speak for Valdosta, GA. We are not a front for a large offshore company.

Mr. DREIER. Well, I cannot speak for California because the chairman did not allow any California witnesses. I know you did not prevent it, Mr. Chairman, but I think that it is—I mean, that is a pretty broad charge, though, and——

Mr. SHOCKEY. One comment I would like to make. Mr. Fields represented FMC Corp., and I have been familiar with that company for 25 years. That is very much an R&D company.

I remember—I think all of their products, but I know that Fidan, one of their proprietary products, came from Herbst in Germany, Keydion came from Philips Roxan, Furadan came from Bayer, the Pyretho came from Japan. So, that is a company that is basically bringing product in from overseas.

Now, they have one product, I believe it is Command, I am not sure if they developed that product, but they have spent millions of dollars in R&D.

Mr. DREIER. And as I said earlier, they make spectacular sweepers in Pomona, CA.

Mr. SHOCKEY. Got to sweep up what they missed.

Dr. STICKLE. Congressman, I would like to add another additional point.

If they are looking at foreign companies, they ought to look to perhaps their own association because 20 to 25 percent of their own members are foreign-owned, and I am sure that they would be willing to supply you with a list and provide that information for you, and there are quite a few, including on their board of directors.

So, I think before they start looking around at other associations, they, perhaps, ought to look at their own association before making such a broad charge.

Mr. DREIER. Well, that is interesting.

This bill, of which I am a cosponsor with my friend, Mr. Hatcher, is one that is designed to address the compensation issue. The bill itself takes a pretty bold step toward the compensation issue, and there is a term that all of you have been using throughout the testimony, reasonable compensation.

I wondered if you could shed a little more light on what you think reasonable compensation is.

Mr. SHOCKEY. What we would, I guess, think would be reasonable, is if a company was compensated for his original expense or part of that expense.

What is happening now is we are being asked to pay 10 times, 20 times the cost of the original data. There are three generic products now that they are talking costs of $40 to $80 million.

Now, back in the days when most of these compounds were developed, they talked—or at that time they represented the cost of developing a new compound to be between $5 and $10 million.

So, for this $5 million data, they now want $80 million. So, we think that if we had some pro rated share of that data, even though it is 17 years old, and maybe a lot of it obsolete, would still be reasonable.

Mr. DREIER. Anybody else want to respond?

Mr. YOUNG. I believe that if they extend the patent, they should not get any data compensation at all. That is what I say is reasonable. Give them 5 more years. That is enough. They are going to get the cost of that data back, and I do not think the farmers should pay for it again.

Dr. STICKLE. What we are really talking about, Congressman, is the opportunity to form a compromise with including patent term restoration and generic registration, and what we are proposing, basically, is to take 17 years and add on the additional 5 years, and say to everyone that you have 22 years to recoup the cost of your R&D, to make your additional profits and realizing that during those 22 years, in fact, very early on through the tax code, every company writes off a significant portion of their expenses for their R&D.

So, the question really is, can they recover their costs for their investment, not only for their winners, which sell 100 million pounds a year, but also for their losses. Can they recoup that in 22 years. That is a very long time, and we submit that we think they can.

Mr. DREIER. What kinds of consumer efforts have been launched? A great argument is made if you reduce the cost to the farmers, that we are going to have a very beneficial impact on the final cost to all of us who are consumers, and it sounds great to have a few small manufacturers, people within the industry raising questions about this and launching the concern, but it seems to me that if we are really going to develop a ground swell within the United States Congress, it is going to have to be a consumer-based concern, and I wonder what kind of effort you all are making to focus attention on that.

Dr. STICKLE. We have met with several of the consumer groups, and we have met with a number of the farm organizations and commodity groups as well.

I would certainly share your point that this is an important consumer issue. It is an important consumer issue as far as farmers are concerned because it will help lower the price of pesticides for farmers, ranchers, pesticide users, and consumers, but it is not just an agricultural issue.

This legislation deals with the agricultural side of the pesticide industry and also the nonagricultural side of the pesticide industry. It does not differentiate. It does not distinguish.

So, what we are talking about, basically, applies to agricultural pesticides and nonagricultural pesticides. What are nonagricultural pesticides? There are a whole variety of products, such as cleansers and cleaners and antimicrobial products. Everything that you find under your kitchen sink or bathroom sink. Any kind of a household insecticide, like Raid, Black Flag, or DeCon. All these are pesticides. Including something as simple as Comet cleanser is defined as a pesticide.

So, Congressman, we are looking at a chemical specialties industry that is very broad and wide sweeping, affects every segment of the American consumers' buying interest.

Mr. DREIER. Now, how are we going to communicate that message to them so that they realize that they can actually see a reduction in costs with the passage of this legislation?

Dr. STICKLE. Well, hopefully, this hearing today is an important step in helping to educate not only Members of Congress, but also the public as well, but I would share with you your concern and your interest to try to help educate the rest of the masses of the people and the Congress as well.

Mr. DREIER. Well, let me just ask you, finally, Dr. Stickle, we heard from Mr. Fields of a 5- to 7-year period for the research and development process. We have a 17-year patent and the statement that the maximum amount of benefit that they have is 11 years of that patent and, yet, it takes 20 years to recoup their costs.

What is your response to that 20 year period?

Dr. STICKLE. Well, Mr. Fields kept coming back to that one example again and again, in essence, saying that was the only example that he had.

I think that is perhaps one example, one opinion from one company. I am not sure that it could not be done much faster than 20 years. If we look at the tax law and we can see exactly how much can be written off in the first year, in the first 3 years, in the first 5 years, a lot of the R&D costs are, in essence, paid for by the American public.

So, we are looking at a situation where companies do recapture their costs.

Mr. DREIER. The problem with that argument, of course, is that it was cut down to 20 percent last year and next year, it expires.

Dr. STICKLE. We are talking about a whole variety of other types of costs, from the laboratory and manpower to the scientists in the laboratory. There are a lot of costs that are written off, and they can be written off in the year that they are incurred.

So, there is a broad variety of costs. We are not just talking about laboratories and physical plants. That is done one time in advance and it is used for the next 15, 20, or 30 years. We are not necessarily talking about that. We are talking about tests that are run, costs that are developed for the development of a particular product, and a lot of these costs, whether they include costs of testing and manpower, can be written off a period of years, and it does not take 20 years to do that.

I am sorry.

Mr. DREIER. So, you do not really place a heck of a lot of credence in that 20 year recoup. I think that is safe to say.

Dr. STICKLE. No, I do not. No, I do not.

Mr. **Dreier**. Thank you very much, gentlemen. I greatly appreciate the testimony, and I appreciate your kindness, Mr. Chairman.

Mr. **Hatcher**. Again, thank all of you for coming. It has been very helpful. Thanks.

We will continue with the third and final panel without a break, and we will announce who you are as this panel leaves.

Mr. Corky Jones, who, I understand, is a farmer and president of American Agricultural Movement, from Brownville, NE; Mr. Doug Campt, Director, Office of Pesticides, Environmental Protection Agency; Dr. Richard Just, professor, Department of Agriculture and Economic Resources, at the University of Maryland, in College Park; Mr. Richard Miller, executive vice president of Prentiss Drug and Chemical Co. in Floral Park, NY.

If there is no objection, we will take your testimony in this order, or have you discussed how you would like to testify? If there is no objection, then we will have Mr. Jones first, Dr. Just, Mr. Campt, and then Mr. Miller.

So, Mr. Jones.

TESTIMONY OF CORKY JONES, FARMER AND NATIONAL PRESIDENT, AMERICAN AGRICULTURAL MOVEMENT, INC., BROWNVILLE, NE

Mr. **Jones**. Thank you, Mr. Chairman.

I am Corky Jones. I am a farmer from Brownville, NE, and I am national president of the American Agricultural Movement. I just stepped off the tractor the day before yesterday, so I am an active farmer. I know a little bit about what farming really entails, and at present, I am farming a 2,800-acre operation, of which 1,400 acres are in corn and 600 acres in soybeans. We have a cattle operation, a hog feeding operation, and three sons are involved with me in this operation.

So, it is a typical general farm. It is typical family farm operation, one which is a demising situation, as you all know, across this Nation.

One of the problems that the farmers face is definitely the high cost of production and one of those high costs of production are agricultural chemicals and the impact that these pesticides have on farmers' cost of production are cash variable expenses.

According to economic statistics recently released by the U.S. Department of Agriculture, pesticides average between 15 and 20 percent of the farmers' cash variable expenses, while the figure is much higher than that on some.

In my testimony and written testimony, there are some charts that were just offered to submit for the record and I will not read them, but in my area of Nebraska, myself and our operation included, we grow corn and soybeans, and for corn, basically, there is about a $17.50 per acre pesticide cost or equivalent to about 9 percent of our cash variable expenses.

If you would have a 500-acre corn crop, you would spend about $8,800 on pesticides for corn. The same holds true, basically, for soybeans in our area, and the same figures apply.

At the same time, Washington is reducing the loan rates and ultimately reducing our net income. We can take a step in the direction of lowering the farmers' cost of production by increasing competition in the pesticide industry and lowering the cost of pesticides to farmers and ranchers.

We cannot give the farmer a real break, a break in the pocketbook, by reducing the cost of pesticides. We are asking why.

During the last 12 years, I, personally, in my own operation as well as across this Nation, have seen what competition in the pesticide industry can do for the American farmer. A major pesticide, Atrazine, an 80-percent wettable powder produced by CIBA-Geigy, was used by many of us in Nebraska and all across this Nation to control weeds in corn and sorghum fields.

During the early seventies, the price of Atrazine was essentially constant with minor fluctuations. In 1977 the price dropped from $2.50 to $2.75 a pound to about $2 a pound. A decrease of roughly 20-percent. The decline in Atrazine prices is directly attributed to expiration of patents in 1976.

Several generic manufacturers entered the market to compete with CIBA-Geigy resulting in lower prices for our pesticides. The national market for Atrazine was about 100 million pounds in 1977 and a drop in price of 50 cents per pound saved $50 million for the farmers. For those farmers that use Atrazine, this was a savings of from $1 to $1.50 an acre. A farmer with 500 acres of corn saved $625 on his production costs.

If the patent on Atrazine had been extended for 5 years, farmers would have had to pay an additional $250 million in higher prices. In the eighties, we saw a repeat pattern with Treflan, a chemical used in soybeans for grass control. Many of my neighbors in Nebraska used this product on soybeans as well as they did across this Nation. In the mid-eighties, it was selling for about $30 a gallon. Treflan went off patent in 1985 and generic products became available in 1986. The price dropped to $21.43 a gallon in my area, a decline of about 28 percent.

As we can see from these examples of Atrazine and Treflan, farmers can get a break on pesticide prices if competition results in generic pesticides. If we can encourage the development of generic pesticides, we can lower the prices of pesticides that farmers buy and reduce the farmer's cost of production. It may be possible to reduce the price of pesticides by 20 percent or more overall.

For those crops like peanuts, cotton, rice, sugar cane, and tobacco, we would be able to save farmers up to $25 per acre in pesticide costs. Without a doubt, no matter what, we can help the farmers reduce the cost of production at a time when the cost of more items purchased by the farmer has been rising higher and higher.

We will submit with this testimony, charts, our charts and those that are submitted from USDA and Economic Research Services. Farmers are also interested in, however, competitively pricing pesticides, especially during this time of economic adversity in order to keep their input costs to a minimum.

When a human drug comes off patent, the generic manufacturer can enter the market simply by demonstrating to the FDA that it is capable of producing the same chemical compound. Not so when a pesticide comes off patent. Current law requires the would-be safety data to EPA in order to get a registration to allow marketing.

The generic producers can either generate their own data, which takes 5 to 7 years, or they can then purchase the right to cite the data previously submitted to EPA according to a complex, lengthy, and costly procedure from the originator.

Generic manufacturers are reluctant to attempt to enter markets when there are potential data compensations. Costs will exceed the profits for many years. Over the next 5 years, 21 pesticides, widely used by American farmers, come off patent. These constitute about 45 percent of the pesticides used by we farmers today.

If these products were available to our farmers from generic pesticide manufacturers, the potential savings could be $4 to $5 million per year. We believe the best way to increase competition in the pesticide industry and lower pesticide prices for farmers and ranchers is to support H.R. 2569, and we in the American Agricultural Movement highly support this.

The Pesticide Price Competition Act was introduced by you, Mr. Hatcher, and we appreciate that. Mr. Chairman, we commend you for your leadership and applaud your efforts to reduce the cost of production for the American farmers. Farmers and ranchers across this Nation, pesticide users and consumers will benefit by generic pesticides and lower prices.

H.R. 2569 eliminates the data compensation provision of FIFRA, after the manufacturer has recouped his research and development costs over the 17 year life of the patent. It provides for an abbreviated application for the registration of generic pesticides similar to the generic drug industry. It is time we did something to advance the interests of the pesticide consumers who would benefit from greater generic competition.

As we look across our land, we discover an agriculture and rural economy suffering from problems, increasing costs of production, growing debts, more problems obtaining credit, declining prices for crops, and we need to move forward to address these concerns.

One way to help the farmers address the increasing costs of production is to face the problem head on. By amending the pesticide legislation, the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA], it is clearly possible, even desirable, to increase competition in the pesticide industry, resulting in reduced pesticide prices and lowering the farmers' cost of production without costing the Government 1 red cent.

We respectfully urge the Congress to adopt H.R. 2569 as part of an overall collection of FIFRA amendments. We urge the Congress to join together to reduce the cost of pesticides for our farmers, thereby lowering his cost for production.

In this way, we can take a positive constructive step in addressing some of the farmers' grievances and help, in part, to reduce some of the economic distress in rural America.

At the same time, I would like to add a little bit that is not on our written testimony. The cry across this land is for we, the farmers, to be more efficient, more productive, competitive with worldwide pricing structures, and, yet, we are looking at a pesticide, insecticide entities, that are trying to go ahead and collect very wealthy profits off of we, the farmers.

Just recently, in the past few weeks, we have had chemical companies obtain Mr. Bill Lesher, past economist with Secretary Block, and fund them for the defeat in Congress—with this entity and advisory group of Mr. Lesher—but fund this entity to defeat the only commonsense piece of legislation in the agriculture industry today, and that is the Harkin-Gephardt bill.

This is the chemical companies that funded this, and we should be working hand-in-hand because this is where their profits are, but the bad part of it is they funded the defeat of the only commonsense thing that is going to be the preservation of the family farmer across this Nation, and they did it with profits, profits obtained from we, the farmers.

Possibly there could be a lot of things that need to be corrected, but this is beyond a doubt one of the things that I think we should go ahead and look into. We should be allies and working with each other, the chemicals and the experimental plots that we have used in our own operation, working hand-in-hand with chemical companies over the years.

I, as a farmer, and many farmers across the land have done this, helping to get workable chemicals that work in all types of soil and all types of climate across this Nation. We have sacrificed, sacrificed our own operation, a lot of expense that we, the producers, have done and helped the chemical companies.

I do not believe that we need to go ahead and extend to them these continued profits. I am sure that they got their expenses back much, much quicker than the 17 years that was indicated by some today.

I certainly thank you for the opportunity to be here, and I will, at least, attempt to answer any of the questions you might have.

[Mr. Jones' prepared statement may be found in the appendix.]

Mr. HATCHER. Thank you, Mr. Jones. Dr. Just.

TESTIMONY OF RICHARD E. JUST, PROFESSOR, DEPARTMENT OF AGRICULTURE AND ECONOMIC RESOURCES, UNIVERSITY OF MARYLAND, COLLEGE PARK, MD

Dr. JUST. Thank you, Mr. Chairman.

Gentlemen, my name is Richard Just. I am a professor of agriculture and resource economics at the University of Maryland.

My interest here today is in addressing the economic efficiency effects of existing pesticide legislation and the economic efficiency impact of the pending bill, H.R. 2569.

The current provisions of the Federal Insecticide, Fungicide, and Rodenticide Act allow the EPA to consider test data submitted by an original pesticide registration applicant in support of registration of other me-too applicants. However, for data originally submitted since 1970, and used within 15 years from the date of original submission, the me-too applicant is required to offer compensation to the original registrant with compensation determined by binding arbitration at the request of either party if agreement cannot be reached.

Some provision that eliminates duplicate testing by follow-on firms is entirely appropriate because the economy as a whole is clearly worse off if costs of testing are multiplied by duplicate testing. However, a great deal of confusion has arisen about what is to be compensated in these arbitrations.

In one case of precedent, *Union Carbide* v. *Thompson Hayward Chemical Co.,* compensation was determined by the administrative law judge by allocating the actual cost of performing the tests among the relevent firms.

In another case you have heard a lot about this morning, *Stauffer* v. *PPG Industries,* on the other hand, compensation was awarded on the basis of the value of profits that could be earned by using the data.

These two approaches lead to compensation amounts that differ by several orders of magnitude. For example, in the latter case, the generic manufacturer was required to pay compensation to the original data submitter in an amount over five times the cost of producing the data.

To further illustrate the differences, in an ongoing arbitration case, an original registrant has requested compensation for: (1) profits for avoiding the cost of pre-registration research; (2) early entry profits due to foregoing the time required for testing following patent expiration; (3) the opportunity costs of regulatory delays experienced by the original registrant; and (4) the opportunity cost of foregone investment on funds used to perform the tests, all in addition to the actual out-of-pocket costs of testing.

If compensation is awarded on this basis, follow-on firms face substantial incentives to do their own testing, which would needlessly increase the testing costs borne by the economy as a whole and delay the benefits of competition gained by the economy following patent expiration.

Even when compensation is awarded on this basis only occasionally, the risk of excessively high compensation will discourage entry and competition in pesticide markets where patents are yet to expire. The large number of pesticides that will come off patent over the next 5 years makes the potential economic efficiency gains from removing this risk substantial.

Compensation, based on the profits that can be earned by using the test data, amounts to effective patent life extension. If an original registrant can extract all the profit that can be earned by use of the test data or, equivalently, all of the profit that can be earned by selling the pesticide, then the incentive for competition following patent expiration is removed, allowing the original registrant to maintain a monopoly in perpetuity.

Furthermore, compensation, in at least one case, was awarded in the form of a royalty, in order to allocate the costs according to market shares, including uncertain future sales. A royalty, in particular, tends to extend effective patent life because it allows the original registrant to earn a profit on the entire market volume, whether or not it remains in the market following patent expiration.

Royalties also impede competition because they distort the price signals to which the follow-on firms react.

If Congress intends for pesticide product developers to have extended patent protection, economic efficiency could be improved substantially by explicitly lengthening the patent protection, such as by H.R. 1345, and eliminating the costly arbitration associated with data compensation.

At present, the power to determine the effective patent protection period has been placed, effectively, in the hands of arbitration panels, who, because they change from case to case, are not sending a consistent signal to the pesticide industry. This imposes unnecessary risk on the industry which causes economic inefficiency.

From the standpoint of economic analysis, the crucial issue here is providing the appropriate tradeoff between inducement for product development and inducement for post-patent generic competition. Higher compensation increases the reward for product development but reduces the reward for post-patent competition. In terms of magnitudes, however, the effects are very different.

For a typical pesticide, the costs of product development are high. There are figures in the range of $30 to $50 million and the probability of success is low.

Furthermore, the majority of pesticides earn most of their profits during the life of the patent, so the probability that a pesticide will have a sufficient market to induce follow-on entry after patent expiration is even smaller.

In contrast to the major costs and returns during the patent life, the potential income from data compensation after patent expiration must be discounted substantially in making the decision to develop a product because it occurs so far in the future.

As a typical discount rate of 10 percent, the value of a dollar of compensation 17 years in the future is less than 20 cents, even excluding considerations for inflation.

Finally, given frequent changes in the legislation, a product developer will likely discount the possibility of compensation even further. All of these considerations imply that data compensation is a minor consideration in inducing the proper level of product development in the pesticide industry.

On the other hand, costs of data compensation are a major factor in inducing the economic benefits of post-patent competition because, first, the costs are incurred soon after the entry decision, second, because the profit margins are typically much lower during post-patent competition, and, third, because post-patent competitors typically gain only a small share of the overall market when they come in.

As a result, errors in determining fair compensation by arbitrators can have a devastating impact on generic competition without producing offsetting benefits from product development.

A final point that I would like to make with emphasis is that the cost of these arbitrations can well exceed any associated economic benefit to the party receiving compensation. To illustrate the point, consider a typical situation where a pesticide is sold exclusively by a patent developer for 12 years following registration and then is sold competitively for an additional 6 years after patent expiration before production becomes unprofitable. As is common, suppose the post-patent competition only succeeds in gaining 20 percent of the market. Then, the post-patent competitors have less than 7 percent of the lifetime market volume, even if the market stays as strong during the post-patent period as during the patent period.

What this means is that even if compensable test costs are high—say in the range of $10 to $15 million—compensation to the original registrant based on lifetime market share allocation of the actual costs is under $1 million.

You have already heard in the testimony of Mr. Whatley, which is in the record, regarding how the total cost of all parties in the current arbitration hearing will likely reach $1.5 million. One of the strongest lessons from economics is that when transaction costs exceed the benefits associated with the transaction, it is time to eliminate the transaction. H.R. 2569 does just that.

Thank you, Mr. Chairman.

Mr. **Hatcher**. Thank you, Dr. Just. Thank you. Next, we will hear from Mr. Doug Campt.

TESTIMONY OF DOUGLAS D. CAMPT, DIRECTOR, OFFICE OF PESTICIDE PROGRAMS, ENVIRONMENTAL PROTECTION AGENCY [EPA], ACCOMPANIED BY ED GRAY, OFFICE OF GENERAL COUNSEL

Mr. **Campt**. Good afternoon, Mr. Chairman and members of the subcommittee.

Thank you for the opportunity to appear before you today to discuss a bill that would amend the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA], H.R. 2569, the Pesticide Price Competition Act of 1987.

Mr. Chairman, I am accompanied by Ed Gray, from our Office of General Counsel, who is prepared to assist in answering questions.

Under FIFRA section 3(c)(1)(D), an applicant for registration is required to support the application by submitting new data or by citing previously submitted data. If the applicant cites data originally submitted by another person, the applicant must either obtain the permission of the original submitter of the data or offer to pay reasonable compensation to the original submitter.

The role of the Environmental Protection Agency [EPA] in this process is to require that the applicant comply with these provisions, and to provide a forum for canceling a registration granted in violation of them.

Disputes about the amount of compensation to be paid, however, are not settled by EPA; instead, the law provides for binding, unreviewable arbitration. The compensation is arbitrated by the Federal Mediation and Conciliation Service.

Mr. Chairman, traditionally, the Agency's position on the issue of data compensation is, simply, that someone other than EPA should determine it. The Agency was established to protect the public health and the environment, not to settle disagreements between businesses about the value of data.

Congress responded to this concern in 1978 by creating the binding arbitration system. It was intended to yield fair, quick, and inexpensive resolutions of data disputes while leaving EPA uninvolved. Me-too registrants argue that this has not happened, and that they are at a competitive disadvantage under the current system.

Your bill addresses the concern of these registrants by simply removing the requirement for data compensation for true me-too products. Passage of this bill would simplify somewhat the processing of these applications by EPA. However, we doubt that the data-generating firms will find it acceptable.

EPA hopes that a solution can be reached to this vexing problem. We urge that you keep in mind the need to minimize demands on Agency resources that should be devoted to protecting health and safety.

In summary, the Agency does not have a position on the bill before us today, but we would welcome action that would resolve a difficult situation.

Thank you very much, Mr. Chairman.

Mr. **HATCHER**. Thank you, Mr. Campt.

I see that counsel kept you quite general, no real commitment. We appreciate your testimony.

Mr. **CAMPT**. Thank you.

Mr. **HATCHER**. Mr. Miller.

TESTIMONY OF RICHARD MILLER, EXECUTIVE VICE PRESIDENT, PRENTISS DRUG & CHEMICAL CO., FLORAL PARK, NY

Mr. **MILLER**. Thank you very much, Mr. Chairman.

I am going to be a little bit liberal with my written text and kind of pick out some of the things that I wanted to cover because most of it has been covered by Mr. Stickle.

Mr. **HATCHER**. We will put the entire document into the record, as you know. So, feel free to highlight it and move about as you will.

Mr. **MILLER**. Mr. Chairman, I am Richard Miller. I am the executive vice president of Prentiss Drug & Chemical Co., Floral Park, NY, and I am a member of the board of directors of the Chemical Producers and Distributors Association.

I would like to also add that our company is a privately held concern being in existence now some 68 years, and our sales volume is under $20 million a year. So, I think we are one of the true small businesses.

I would also like to add that I do not want to get confused with the drug part of it. That goes back to the origin of the company, at which time we were in the botanical drug business, which we exited some 30 years ago.

The research-intensive chemical companies are claiming that they need enactment of patent term restoration so that they can increase innovation. I would like to take a look at the effect of patent term restoration when it was coupled with generic registration as it benefited the pharmaceutical industry.

Since 1984 there have been no declines in drug research and development funds, only increases of about 14 percent for 1985 and for 1986. In the past 2 years, an additional $1 billion has been poured into drug R&D. Research and development has actually doubled since 1981 and it has actually doubled nearly every 5 years since 1961 in that industry.

In fact, the number of generic applications in the pharmaceutical industry rose from 470 in 1984 to 1,069 in 1985, which was an increase of over 125 percent. Of these 1,069 applications, 389 were approved. In 1986 there were 1,062 generic applications and 616 were approved. We expect that this trend will probably continue.

We feel that the agricultural chemical companies will probably not discontinue or reduce their R&D budgets by $100 million a year as they mentioned in last year's testimony on the bill, which is before the Agriculture Committee. We feel that they will, indeed, probably continue to increase it because there is a great deal of money at stake here by way of additional profits on new chemicals.

I would like to also address the issue of tax laws. The tax laws provide major incentives for research and development in spite of the removal of R&D credits. One of the largest portions of the cost of R&D is the salaries of the people involved in R&D. That is expensed in the current year.

We will always continue to have, at some rate, a depreciation schedule for the buildings involved and there will always be expenses or consumable items that are consumed in the R&D process. So, the taxpayers already are bearing a very major portion of the cost of R&D in industry.

Another central argument raised in favor of patent term extension is that innovation is declining under the existing law. The amount being spent on research and development is not declining. The U.S. chemical industry, including but not limited to pesticides and other farm chemicals boasted profits of $4.25 billion in 1986, which was an 8-percent increase over the previous year.

Other companies, which were looked at in the Business Week R&D scoreboard, which is the June 22, 1987, issue, on pages 144 and 145, that survey reported profits as high as 15 percent above 1985 levels. Another gauge of the state of the chemical industry is R&D expenditures for the year. The average annual R&D expenditure was 6 percent in 1986, with some companies posting R&D expenditures as high as 11 and 14 percent according to Business Week.

The chemical industry appears to have no need to worry about a potential decrease in R&D following the implementation of generic registration, given these figures. Also, chemical companies are pouring a considerable percentage of their profits back into R&D. In fact, the industry reported that an average of 48.6 percent of its pretax earnings went directly into its R&D facilities during 1986.

Nearly half of the Nation's chemical industry's profits went directly into research for creating new chemicals, chemicals that will benefit U.S. consumers, and, for the portion pertaining to the pesticide industry, the farmers.

Some members of the chemical industry reported higher figures. One company reported that 95.9 percent of its pretax earnings were recycled into its R&D projects.

I do not believe that these figures reflect an industry where R&D is drying up at all.

The National Agricultural Chemical Association itself, in its own surveys of 1984 and 1985, reveals significant increases in R&D pertaining to that segment of the industry. R&D increased by as much as 39.3 percent in 1984 and 18.9 percent in 1985, in spite of what we all know is a terrible year for the farmers.

We see no reason why the American agricultural chemical industry would cut back its R&D expenditures. In general, as I said, R&D costs are usually recovered within a few years, if only because firms would not invest in products where they would expect a low rate of return.

We fully realize the importance of research and development for the pesticide industry and the need to generate new chemicals for future needs. Farmers, consumers, and pesticide users depend on the development of new products to increase crop yield, protect against serious infestations, and improve the quality of life for all Americans.

We support H.R. 2569 because it is not intended to deprive basic manufacturers from recouping their R&D costs for successful and unsuccessful products, as well as receiving an ample return on their investment.

The current law in the 1987 proposed amendments go to great lengths to protect the investment interests of the original manufacturer, but we have done nothing to advance the interests of the farmers, ranchers, users, and consumers who would benefit from greater generic competition and lower prices.

We hope that your bill will do that, and we think that it is high time to resolve this long-standing inequity.

I would like to add just a couple of remarks about some earlier testimony. It was brought up by Mr. Fields that the research and development companies were bearing the brunt of data call-in responses. I know this not to be true.

We are involved in a couple of data call-in responses right now, and we are not an R&D nor a basic manufacturer.

Any company holding a technical chemical registration is responsible for replying to a data call-in and, therefore, must in some way arrange to supply the data necessary in order to maintain its registration or they will forfeit that registration.

In addition, I would like to add a little support to the theory, or actually I would like to contest the theory, that some of the small companies entering this market are, in a way, leaching off of the large companies. A lot of small companies entering this market will be using the profitability and sales generated by generic chemicals to enter the R&D scene. It takes a big investment. A company the size of mine cannot even remotely consider a $15 million investment in a new chemical, considering the fact that so many of them do fail.

You have to build some volume and some profitability for your company before you can become an R&D company, and that is where competition begins.

With regard to the comments about it taking 20 years to develop—to recover the costs of an average $40 million chemical, I would maintain that the chemical companies are not in there to be involved in $40 million a year chemicals. There are some chemicals that are selling for $200–300–400 million in volume a year, and the profitability of those chemicals doubtless recovers their costs much earlier than the 20-year period stated.

I do not think that any reasonable businessman would want to take on a chemical that he did not think was going to recover the cost he invested in it and give him a return on his money.

I would also like to just address the data compensation provision rather indirectly in that I think it is important to point out that much of the data for which compensation is being paid does no longer meet current EPA protocols. Were that data to be submitted today as new data, it would not even be accepted. That is probably the biggest failing of the whole compensation issue.

You are paying for something that is no good.

Thanks very much for the opportunity to address the committee.

[Mr. Miller's prepared statement, with attachments, may be found in the appendix.]

Mr. HATCHER. Thank you.

I have just a question for Mr. Campt.

Mr. Campt, did you hear the testimony about whether or not there is a relationship, and, if so, what the relationship is between how you should treat these matters in the pharmaceutical industry and the pesticide industry?

Mr. CAMPT. Yes; I heard that.

Mr. HATCHER. Well, do you have an opinion or does EPA have an opinion about that issue?

Mr. CAMPT. Well, there are some similarities, a lot of similarities, between the drug situation and the pesticide situation.

There are some differences, however, in terms of the data that we receive. Now, with respect to the drugs, a lot of data is submitted to FDA on the efficacy of the drug. We have waived this submission of efficacy data on most agricultural products.

One other difference with which we are concerned—heavily concerned—is environmental fate, fish, and wildlife data, and agricultural chemicals.

Now, to that extent, there are differences, but the systems are similar in a lot of respects.

Mr. HATCHER. Well, again, let me thank all of you for taking time to be here. Your testimony has been helpful and we appreciate it.

That concludes the hearing.

[Whereupon, at 12:35 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

APPENDIX

PREPARED STATEMENT OF CHAIRMAN HATCHER

HEARING ON H.R. 2569

JUNE 24, 1987

Good morning. I want to thank you all for taking time out of your busy schedules to be with us this morning. I'm Charles Hatcher, and I chair the Subcommittee on Energy and Agriculture, which is holding this hearing today. This morning we will be looking into the impact of H.R. 2569 on small agri-chemical companies, farmers, and consumers.

H.R. 2569 is aptly titled the Pesticide Price Competition Act of 1987, because competition is what this bill is all about. H.R. 2569 would amend the Federal Insecticide, Fungicide and Rodenticide Act, known as FIFRA, to establish generic pesticide registration after a product's 17-year patent expires. I believe this legislation would result in more competition within the pesticide industry, and ultimately lower prices for pesticides.

This bill is vitally important to small agri-chemical companies throughout our country because it would facilitate their entrance into the market by allowing generic pesticide production. A strong corollary can be drawn between human drugs and pesticides. At present, when a human drug's 17-year patent expires, a generic drug manufacturer can enter the market by demonstrating to the FDA that it is capable of producing the same chemical compound. However, when a pesticide product's 17-year patent expires, the small chemical company has two options. One option is to generate the same data that has already been produced by the previous registrant, which takes five to seven years. The other option is to purchase the right to this data, which is a complex and lengthy process, as well as cost prohibitive. Neither of these options are feasible for small companies.

This situation is simply not fair to small businesses or to farmers or to consumers. We need to change the data compensation provisions of FIFRA to correct this unfair situation. H.R. 2569 would make the necessary changes, which would result in increased competition in the pesticide industry and lower prices for farmers and consumers.

This morning we are going to hear from a number of people both for and against this bill. I am certainly looking forward to hearing what everyone has to say, and I am sure we will all learn something. Once again, I would like to thank everyone who is participating in this hearing today.

At this time I would like to call on Congressman Dreier, the ranking minority member of the Subcommittee, for any opening remarks he would like to make.

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House of Representatives

THE PESTICIDE PRICE COMPETITION ACT

HON. CHARLES HATCHER

OF GEORGIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, June 25, 1987

Mr. HATCHER. Mr. Speaker, I have introduced H.R. 2569, the Pesticide Price Competition Act, which will establish generic pesticide registration, stimulate increased competition in the pesticide industry, and lower the price of pesticides for farmers, ranchers, users and consumers across this country. This legislation is identical to S. 746, a companion bill introduced in the Senate by Senators NANCY KASSEBAUM and AL GORE.

The purpose of this legislation is twofold: to lower the farmer's cost of production by reducing the cost of pesticides, and to reduce the cost of nonagricultural products that consumers buy. This measure could save farmers from $400 million to $500 million per year for at least the next 5 years on agricultural pesticides alone. Consumers could save additional millions on nonagricultural products.

As we look across our land, we discover an agricultural and rural economy suffering from problems—increasing costs of production, growing debts, obtaining adequate credit, declining prices for crops—and we need to move forward to address these concerns. One way to help the farmer meet the increasing costs of production is to amend the pesticide legislation, the Federal Insecticide, Fungicide and Rodenticide Act [FIFRA]. This would help the farmer immeasurably, without any cost to the Government.

According to recent figures in the Economic Indicators of the Farm Sector, Cost of Production, 1985, prepared by the U.S. Department of Agriculture [USDA], pesticides average between 10 and 35 percent of farmers' cash variable expenses—seed, fertilizer, chemicals, hired labor, and so forth. Farmers across this country apply agricultural pesticides to their crops, and these costs clearly comprise a significant percentage of their annual expenses.

In the southeastern United States, farmers face a tremendous challenge. Cotton farmers across the Nation spend an average of $45 per acre for chemicals, while these farmers in the Southeast use $96 of pesticides per acre. Peanut farmers average $30 per acre for chemicals, but Southeastern peanut farmers average close to $95 per acre, and Virginia and North Carolina farmers average $69 per acre. Like the Hawaiian sugar cane growers and Texan sugar beet producers, Southeastern farmers pay a disproportionate share of their cost of production on agricultural chemicals.

However, we can lower the price of pesticides, thereby reducing the farmer's cost of production, if we encourage the development of generic pesticides. In fact, it may be possible to reduce the price of pesticides by 10 to 20 percent or more. One way to reduce these prices is to eliminate the data compensation provision of FIFRA. When generic pesticide producers enter the market following the expiration of a patent, they generally capture only 10 to 20 percent of the existing market. Yet the overall impact on prices can be significant. For example, prices of three commonly used pesticide products—phostoxin, treflan and sutan—dropped an average of 18.1 percent after generic products entered the marketplace, resulting in significant savings to farmers and other pesticide users.

The data compensation issue is critical at this time. During the next 5 years, 21 patents for pesticides widely used by American farmers will expire. These pesticides constitute 45 percent of all chemicals used by farmers today. If these products were available to our farmers from generic pesticide manufacturers, the potential savings could be $400 million to $500 million per year.

Agricultural chemicals, including pesticides, have made enormous contributions to the productivity of agriculture and the quality of farm produce. Basic manufacturers of pesticides spend hundreds of millions of dollars on research and development [R&D] of new products. I commend them for this innovative effort. Farmers need the effective pesticides that R&D generates; they depend on the development of new products to increase crop yield and protect against serious infestations. However, farmers also are in desperate need of competitively priced pesticides, especially during this time of economic adversity, to keep their production costs to a minimum.

H.R. 2569 is not intended to deprive basic manufacturers from recouping R&D costs for successful or unsuccessful products, or from receiving an ample return on their investment. Under current law, there is a 17-year exclusive marketing right on registered pesticides to protect the rights of the original manufacturers. In addition, manufacturers are eligible for research and development tax deductions and credits.

I agree that innovators in the pesticide industry should expect to recover the cost of research and development, assuming all other conditions are equal. But I do not think that the body of law regulating how pesticides are registered and marketed should be tilted so heavily toward the basic producer and away from the generic producer. The current law and the 1987 proposed amendments go to great lengths to protect the investment interests of the original manufacturer, but we have done nothing to advance the interests of the farmers, ranchers, and consumers who would benefit from greater generic competition and lower prices.

H.R. 2569 calls for the removal of the data compensation provision of FIFRA. Under the existing FIFRA law, developers of agricultural pesticides or chemicals may market that product for 17 years without competition. However, these barriers to market entry do not end with the expiration of a pesticide patent. After the patent expires, any company wishing to produce a generic version of that product has two options. The producer may choose to spend from 5 to 7 years duplicating the original research, or the producer may pay the original manufacturer for the research involved in the creation of the product. Both options are cost prohibitive and unreasonable.

In addition, if a generic manufacturer opts to do his own testing for 5 to 7 years, the basic manufacturer is granted a de facto extension of the patent for these same 5 to 7 years, and the consumer faces continued high prices. If the 17-year patent life is extended by 5 years of patent term restoration, as provided by H.R. 1345, and an additional 5 to 7 de facto testing years are also added, the basic manufacturer would have a monopoly on the product for 27 to 29 years. On the other hand, if the generic manufacturer opts to pay data compensation under FIFRA for the privilege of citing data generated by the basic manufacturer, the generic manufacturer faces a serious dilemma. FIFRA does not contain a specific standard for determining the amount of compensation. Therefore, generic manufacturers will not know in advance the amount of compensation involved. They are, in effect, asked to buy a pig in a poke. The amount of data compensation is determined by a system of binding arbitration set up by the 1978 amendments to FIFRA, and can be an extremely costly process. For example, in the 1983 Stauffer Chemical Company versus PPG Industries case, the arbitration award amounted to 50 percent of the cost of the data plus a 10-year royalty. In all, the value of the award exceeded $15 million, which was five times the actual cost of producing the data. Most generic manufacturers are small businesses that cannot operate in such an ambiguous and uncertain economic atmosphere.

This situation discourages generic manufacturers from market entry, and acts as a barrier to competition. Most importantly, whichever of the two approaches is pursued, farmer access to generic pesticides is delayed. It also means that, because of the cost involved, the price of the generic product will not be as low as it otherwise could be.

We need only examine the generic drug industry to see how pesticide users would benefit from a similar generic pesticide industry. When a human drug's patent expires, a generic manufacturer can enter the market simply by demonstrating to the FDA that it is capable of producing the same chemical compound. Generic drug manufacturers are not forced to pay for data filed with the FDA or to duplicate costly research. As we are all aware, consumers have clearly benefited from inexpensive, and often lifesaving, drugs.

H.R. 2569 is patterned after the generic drug legislation that passed the Congress in the fall of 1984, and provides for the use of an abbreviated application for the registration of generic pesticides. When we granted patent term extension for drug products in 1984, we removed some of the barriers that made it difficult for generic drugs to enter the marketplace. We are proposing the same treatment for pesticides with expired patents.

It appears that the present administration approves of this approach. In a letter dated March 10, 1986, Health and Human Services Secretary Otis Bowen wrote Senator STROM THURMOND in strong support of restoring lost patent time due to Federal premarket requirements for veterinary drugs, pesticides and agricultural chemicals. The complete text of Secretary Bowen's letter appears in the CONGRESSIONAL RECORD on March 13, 1987, page S3179.

The basic manufacturers of pesticides are continuing to push for patent term restoration. I would strongly argue, however, that if we are to provide patent term restoration for pesticides, then we must change the present system for registered generic pesticides on the market. We must make it possible for the generic producer to enter the market once a pesticide's patent expires, whether that be 17 or 22 years, and without paying an excessive penalty for the right to enter the market. To grant patent term restoration while at the same time retaining the present system for the registration of generic pesticides would be a great injustice to the American farmer.

Last year the House passed H.R. 2482 and the Senate passed S. 2792. Both of these bills contained a provision for patent term restoration of up to 5 years. In each case, however, there was no provision to expedite the manufacturing of generic pesticides. I offer H.R. 2569 as a compromise to resolve the dispute over the business issues of FIFRA. In each of the last three Congresses, efforts to amend FIFRA have been frustrated by an inability to resolve disagreements over business issues within the pesticide industry.

Now is the time to offer a compromise that would create generic pesticide registration and increase competition while lowering prices for farmers and consumers. If combined with H.R. 1345 and H.R. 2463, introduced by Congressmen GEORGE BROWN, KIKA DE LA GARZA, EDWARD MADIGAN, PAT ROBERTS, and others, it would be possible to aid the basic pesticide manufacturers, generic producers and consumers. In a spirit of compromise, I offer this legislation as a means of resolving one of the most complex and controversial aspects of FIFRA legislation. If Congress fails to act on this matter, we will be doing a great economic injustice to the American farmer.

By adopting this legislation as part of a larger FIFRA amendment package, the Congress would inject a healthy dose of competition into the pesticide industry. And the farmers and consumers would benefit enormously without any cost to the Government.

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America Needs Parity!

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TESTIMONY FOR

CORKY JONES, NATIONAL PRESIDENT

AMERICAN AGRICULTURE MOVEMENT, INC.

ON

PESTICIDE PRICE COMPETITION ACT
H.R. 2569

WEDNESDAY, JUNE 24, 1987

BEFORE THE

SUBCOMMITTEE OF THE SMALL BUSINESS COMMITTEE

ON

ENERGY AND AGRICULTURE

CHAIRMAN CHARLES HATCHER

Mr. Chairman, I am Corky Jones, a farmer from Brownville, Nebraska. I am President of the American Agriculture Movement (AAM) and appreciate the opportunity to be here to share with you some of the problems that farmers are facing.

At present, I farm 2800 acres, of which 1400 are in corn and 600 are in soybeans. In the real world of agricultural economics, American farmers are struggling and, in some cases, are facing economic ruin, foreclosure and bankruptcy.

One of the problems that farmers face is the high cost of agricultural chemicals and the impact that these pesticides have on farmer's cost of production or cash variable expenses. According to economic statistics recently released by the U.S. Department of Agriculture, pesticides average between 15 and 20 percent of the farmer's cash variable expenses, while the figure is as high as 36 percent for some crops.

PESTICIDES AND THE COST OF PRODUCTION

Crop*	1985 cost of chemicals per acre	1985 chemical percentage of cash variable expenses
Corn	$17.58	8.6%
Sorghum	8.52	13.4%
Barley	5.43	10.4%
Oats	1.11	.3%
Wheat-all	2.93	5.9%
Spring wheat	5.09	12.5%
Durum wheat	5.35	14.2%
White wheat	9.58	12.9%
Winter wheat	1.50	3.3%
Rice	26.88	10.8%
Soybeans	17.47	32.3%
Sunflower	13.30	27.3%
Peanuts-all	79.63	29.3%
" southeast	94.58	33.0%
" VA & NC	88.76	28.7%
Flax	4.15	13.6%
Cotton-all	45.18	20.5%
" Delta	72.27	32.3%
" southeast	96.04	35.7%
Sugar beets	44.57	15.3%
" TX & NM	101.13	22.9%
Sugar cane	56.44	7.5%
" Hawaii	125.64	4.8%
Tobacco**		
" burley	$70.08	3.6%
" flue-cured	94.44	4.6%

* Economic Indicators of the Farm Sector, Costs of Production, 1985 (United States Department of Agriculture, Economic Research Service), ECIFS 5-1.
** Annette Clausen, Economic Research Service, USDA.
*** Chemical category does not include fertilizers

In my part of Nebraska, many of my neighbors grow corn and soybeans. For corn, we spend about $17.50 per acre for pesticides, or about 9 percent of our cash variable expenses. If you have a 500--acre corn crop, you would spend about $8,800 on pesticides. For soybeans, we also spend about $17.50 per acre on pesticides, but it is about 32 percent of our cash variable expenses. Again, on a 500-acre soybean crop, we would spend about $8,800 for pesticides.

Washington is reducing the loan rates and, ultimately, reducing our income. We can take a step in the direction of lowering the farmer's cost of production by increasing competition in the pesticide industry and lowering the cost of pesticides to farmers and ranchers? Why can't we give the farmer a real break--a break in the pocketbook--by reducing the costs of pesticides?

During the last 12 years, I have seen what competition in the pesticide industry can do for the American farmer. A major pesticide--atrazine, an 80 percent wettable powder (produced by Ciba Geigy)--was used by many of my Nebraska neighbors to control weeds for corn and sorghum. During the early 1970's, the price of atrazine was essentially constant, with minor fluctuations. In 1977, the price dropped from $2.50-$2.75 a pound to about $2 per pound, a decrease of at least 20 percent. The decline in atrazine prices is directly attributable to expiration of the patent in 1976. Several generic manufacturers entered the market to compete with Ciba Geigy, resulting in lower prices for our pesticides.

The national market for atrazine was about 100 million pounds in 1977. A drop in price of 50 cents per pound saved $50 million. For those farmers who used atrazine, there was a savings of $1.25 to $1.50 per acre. A farmer with 500 acres of corn saved $625 on his cost of atrazine. If the patent on atrazine had been extended for five years, farmers would have had to pay an additional $250 million in higher prices.

In the 1980s, we saw a repeat pattern with treflan. Many of my Nebraska neighbors use this product on soybeans. In the mid-1980s, it was selling for about $30.00 a gallon. Treflan went off patent in 1985 and generic products became available. In 1986, the price dropped to $21.43 a gallon, a decline of about 28 percent.

As we can see from these examples of atrazine and treflan, farmers can get a break on pesticide prices if competition results in generic pesticides.

If we can encourage the development of generic pesticides, we can lower the prices of pesticides that farmers buy and reduce the farmer's cost of production. It may be possible to reduce the price of pesticides by 20 percent or more. For those crops like peanuts, cotton, rice, sugar cane and tobacco, we might be able to save farmers up to $25 per acre in pesticide costs. Without doubt, however, we can help the farmer reduce the cost of production at a time when the cost of most items purchased by the farmer have been rising higher and higher.

ENACTMENT OF GENERIC PESTICIDE LEGISLATION COULD MEAN SIGNIFICANT SAVINGS FOR THE FARMER

Crop*	1985 cost of chemicals per acre***	Savings per acre if prices drop 20% due to generic competition
Corn	$17.58	$3.52
Sorghum	8.52	1.70
Barley	5.43	1.09
Oats	1.11	.22
Wheat-all	2.93	.59
Spring wheat	5.09	1.02
Durum wheat	5.35	1.07
White wheat	9.58	1.92
Winter wheat	1.50	.30
Rice	26.88	5.38
Soybeans	17.47	3.50
Sunflower	13.30	2.66
Peanuts-all	79.63	15.93
" southeast	94.58	18.92
" VA & NC	88.76	17.75
Flax	4.15	.83
Cotton-all	45.18	9.04
" Delta	72.27	14.45
" southeast	96.04	19.21
Sugar beets	44.57	8.91
" TX & NM	101.13	20.21
Sugar cane	56.44	11.29
" Hawaii	125.64	25.13
Tobacco**		
" burley	$70.08	$14.02
" flue-cured	94.44	18.89

* *Economic Indicators of the Farm Sector, Costs of Production, 1985* (United States Department of Agriculture, Economic Research Service), ECIFS 5-1.
** Annette Clausen, Economic Research Service, USDA
*** Chemical category does *not* include fertilizers

Farmers are also interested however, in competitively priced pesticides, especially during this time of economic adversity, in order to keep their input costs to a minimum.

When a human drug comes off patent, a generic manufacturer can enter the market simply by demonstrating to the FDA that it is capable of producing the same chemical compound. Not so when a pesticide comes off patent. Current law requires the would-be safety data to EPA in order to get a registration to allow marketing. The generic producers can either (1) generate their own data, which takes five to seven years, or (2) they can purchase the right to cite the data previously submitted to EPA according to a complex, lengthy and costly procedure from the originator.

Generic manufacturers are reluctant to attempt to enter markets when their potential data compensation costs will exceed their profits for many years.

Over the next five years, 21 pesticides widely used by American farmers come off patent. These constitute about 45 percent of all pesticides used by farmers today. If these products were available to our farmers from generic pesticide manufacturers, the potential savings could be $400 million to $500 million per year.

We believe that the best way to increase competition in the pesticide industry and lower pesticide prices for farmers and ranchers is to support H.R. 2569, the Pesticide Price Competition Act, introduced by Congressman Charles Hatcher. Mr. Chairman, we commend you for your leadership and applaud your efforts to reduce the cost of production for the American farmer. Farmers, ranchers, pesticide users and consumers will benefit by generic pesticides and lower prices.

H.R. 2569 eliminates the data compensation provision of FIFRA after the manufacturer has recouped his research and development costs over the 17-year life of the patent. After these 17 years, it provides for an abbreviated application for the registration of generic pesticides, similar to the generic drug industry. It is time we did something to advance the interests of the pesticide consumers who would benefit from greater generic competition.

As we look across our land, we discover an agricultural and rural economy suffering from problems--increasing costs of production, growing debts, more problems obtaining credit, declining prices for crops--and we need to move forward to address these concerns. One way to help the farmer address the increasing costs of production is to face the problems head on. By amending the pesticide legislation, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), it is clearly possible, even desirable, to increase competition in the pesticide industry, resulting in reduced pesticide prices and lowering the farmer's cost of production, without costing the government a penny!

We respectfully urge the Congress to adopt H.R. 2569 as part of an overall collection of FIFRA amendments. We urge the Congress to join together to reduce the cost of pesticides for our farmers, thereby lowering his cost of production. In this way, we can take a positive, constructive step in addressing some of the farmers' grievances and help, in part, to reduce some of the econmic distress plaguing rural America.

PREPARED STATEMENT OF GEORGE MILLER, VICE PRESIDENT, TRANS CHEMIC INDUSTRIES, INC.

The United States is currently facing a crisis which threatens the very existence of the American farm family. Costs of crop production are often higher than the market sale price of those crops. This is especially true of agricultural commodities where we compete on an international level. Even with extremely low farm prices, our agricultural commodities are simply not competitive with commodity producers overseas.

The value of the American dollar has decreased on international markets and we remain in a non-competitive situation. There are several reasons that we are not competitive in these commodities, but one significant reason is the cost of pesticides to the American farmer.

The American farmer is actually paying more for his pesticides than farmers working in such areas as Central and South America. Countries all over the world are exporting to the Southern Hemisphere at low prices. Even pesticides produced in the United States are generally available abroad at prices far less than the domestic price level. There are many examples of the pesticide price difference versus the prices in the United States. The following chart notes a few pesticide prices overseas versus prices available on the U.S. market:

Product	U.S. Price 1984	International Price
Malathion	$1.55-1.65/lb.	$.82-.95/lb.
Methyl Parathion	1.55/lb.	.92-1.05/lb.
Carbaryl	2.55/lb.	1.85/lb. (Spain)
Treflan	26.00/gal.	16.00/gal.
Paraquat	32.00-36.00/gal.	13.00/gal.

There are even products that, while still patented in the U.S., exhibit a large price difference on U.S. and foreign markets because, in many countries, patents expire in 12 to 15 years, not 17, as in the U.S.

Product	U.S. Price	Foreign Price
Roundup	$68.00/gal.	$42.00-44.00/gal.

Even when patents expire, new entry into the market may still be difficult in some cases because generic producers must still register their version of the chemical with EPA. The EPA has attempted to reduce the time lag by using data submitted by the original registrant under 3 (C) (1) (D) of FIFRA. This action in turn has stimulated law suits brought by the original registrants who insist on receiving compensation for the data. Such legal action can ensure that generic registrations are delayed in court for a lengthy period, effectively lengthening the life of a patent.

The cost of chemicals per acre and the chemical percentage of the cash variable expenses for the U.S. farmer give a clear indication of the problem. (See Addendum 1).

Crop	1985 cost of chemicals/acre	1985 chemical % cash variable expense
Corn	$17.58	8.6%
Spring Wheat	5.09	12.5%
Durham Wheat	5.35	14.2%
Rice	26.88	10.8%
Soybeans	14.47	32.3%
Peanuts (all)	79.63	29.3%
Cotton (all)	45.18	20.5%

CPDA feels that one of the reasons for the price difference in pesticides is the artificial barriers present in the United States Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) which regulates the registration of pesticides, the Bolar/Roche decision and the duplicative testing made necessary by individual state pesticide laws.

Registration of Pesticides:

Registration of pesticides creates an artificial barrier that increases prices of pesticides to our growers because of the data compensation provisions found in FIFRA.

To register a generic pesticide today, an applicant must:

1) duplicate data already in EPA files, or
2) cite specific data of another registrant and provide product specific data and offer compensation, or
3) cite all data in EPA files and offer to pay compensation.

In all cases, you are artificially adding to the cost of a generic product and significantly increasing the time involved in placing a generic product in the marketplace.

Duplicating existing data already present in EPA files, is not only costly, unnecessary and a waste of laboratory resources, but is also an artificial barrier put in place by law.

Citing specific data of another registrant while producing product specific data and offering to pay compensation is also an artificial barrier. Why should a generic applicant have to cite old data and offer compensation on old data when that information already exists?

Citing all data of other registrants in EPA files and offering to compensate for the uses of the data is another artificial barrier of data compensation which appears to have been created only to obstruct the generic registration process.

What is the purpose of data compensation? And what exactly is the follow-on registrant paying for? The answer is the original data used to register a pesticide product which, in all probability, did not cost the original data submitter anything. Why? Because the cost of the data was probably written off by the producer of the data in the year the costs were incurred as specified under current tax laws. That means that the United States taxpayers, that is, you and I, paid for the data and that data should belong to the general public. If the data belongs to the public, then we see the way clear to removing the biggest artificial barrier of all, data compensation.

Congress wisely gave the pharmaceutical industry generic registration. When a drug now comes off patent, a generic producer can enter the market simply by proving that his product is substantially similar to the original product. This law has saved the general public millions of dollars over the few years it has been in effect. The same would hold true if a generic pesticide law were to be enacted. The same type of savings could be passed on to American farmer and the American consumer.

Our farmer could be more competitive on international markets and more profitable on domestic markets. The grocery bill for the American consumer would reflect savings in the cost of their produce and other products. Generic registration would add competition to an industry that presently has all the looks of a monopoly and might even entice one of our large basic manufacturers to produce generic products.

Monopoly is the operative word here. The pesticide industry is currently very concentrated, with 10 companies controlling 66 percent of the world pesticide market. The U.S. market had been maintained in a fairly competitive mode before 1978 due to the moderate rate of turnover of leading products, allowances for generic registrations under section 3 (C) (D) (1) of FIFRA and patent expiration. However, unreasonable data compensation decisions under this portion of FIFRA are reducing the number of new entrants into the market on non-patented pesticides. As competition in the market decreases, the incentive to be innovative also decreases, a generally recognized empirical result of most industrial organization studies.

The major companies would have you believe that technology is being exported by allowing the use of data for a generic registration when, in fact, technology and data are being imported into this country.

The top ten agricultural chemicals in the world are:

Company	Country	U.S. Name
Bayer	Germany	Mobay
Ciba Geigy	Switzerland	Ciba Geigy
Monsanto	U.S.	Monsanto
Shell	U.S.	Du Pont
ICI	Great Britain	ICI America
Rhone Poulenc	France	Rhone Poulenc
Dow	U.S.	Dow
Hoechst	Germany	American Hoechst
Du Pont	U.S.	Du Pont
BASF	Germany	BASF

The top three companies, Bayer, Ciba Geigy and Monsanto, account for 31 percent of the world pesticide sales. The next seven companies account for the next 35 percent of sales worldwide.

These same 10 companies are the largest importers of pesticides into the U.S. The National Agricultural Chemical Association (NACA) Industry Profile Study states that U.S. sales of non-U.S. production has remained about the same: $1,379 million in 1983, $1,366 million in 1984, and $1,318 million in 1985, or about 25 percent of U.S. production.

Effects of the Generic Drug Industry:

The pharmaceutical industry seems to be enjoying great prosperity now that generic drug registration is law. Major pharmaceutical companies have seen the light and because of generic registration have added a number of new products and started generic production. A great savings has been enjoyed by people on fixed income. These same people on fixed incomes could benefit from a similar generic pesticide law and could see a real savings in their weekly grocery bill.

We must stop the great disparity in prices between our pesticides used by overseas growers and the American farmer. We must eliminate the artificial barriers which force the American farmer to pay more for his pesticides. We must make the American farmer more competitive in the world marketplace.

CPDA submits that a generic pesticide registration bill will go far to achieve those aims.

Prepared Statement of Richard Miller, Executive Vice President, Prentiss Drug & Chemical Co.

Mr. Chairman, I am Richard Miller. I am Executive Vice President of Prentiss Drug and Chemical Company, Floral Park, New York, and a member of the Board of Directors of the Chemical Producers and Distributors Association. I would like to take a few moments to compare research and development in the drug and pesticide industries, and to comment on the impact that generic registration would have on innovation in the pesticide industry.

Research intensive chemical companies claim that they need the enactment of patent term restoration so they can increase innovation.

In 1986, the Committee for Research and Development of Agricultural Chemicals, composed of 11 basic manufacturers, warned the Congress:

> "If Congress amends the FIFRA to allow low-cost access to health and safety data for follow-on registrants,...private sector R&D in agrichemicals will decline by $100 million or more each year -- from a base of $553 million in 1985..."

The leaders of the agrichemical industry would have us believe that, in five or six years, research and development would almost diappear! Does anyone really believe this misleading rhetoric? Is the agrichemical industry crying wolf?

Are these misleading statements from the agrichemical industry leaders reminiscent of the statements issued by the drug manufacturers during the congressional debate in 1983-1984 about establishing generic drug registration? What did the Pharmaceutical Manufacturers Association (PMA) state on July 25, 1983? The following statements represent their views on R&D in 1983:

> "Innovation will dry up."
>
> "...it [H.R. 3605] nonetheless strives to reduce economic incentives for important pharmaceutical research still further."
>
> "But whatever short-term savings may be acheived will come at an enormous long-term cost to the public in terms of reduced pharaceutical research, fewer new medicines in the future..."[1]

But has R&D in the pharmaceutical industry dried up in the last few years or in the period since the passage of the generic drug bill? What are the facts?

Since 1984, there have been no declines in drug research and development funds, only increases--about 14 percent per year for 1985 and 1986!! In the past two years, an additional $1 billion has been poured into R&D. Research and development has actually doubled since 1981! And has doubled nearly every five years since 1961!!

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[1] Portion of statement of the Pharmaceutical Manufacturers Association (PMA) before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives, on H.R. 3605 on July 25, 1983.

	R&D Human & Veterinary (millions)	Percentage increase	Actual increase
1986	$4,647	13.95%	569,000,000
1985	$4,078	13.94%	499,000,000
1984	$3,579	10.86%	361,000,000
1983	$3,218	18.97%	444,000,000
1982	$2,774	18.00%	433,000,000
1981	$2,340	18.36	363,000,000

(See Appendix VI.)

What about the dire prediction of innovation drying up? Of interest in R&D declining? No longer do we hear these outlandish predictions of doom.

In 1984, Congress provided the pharmaceutical industry with patent term restoration, but it also eliminated the Bolar/Roche decision, and provided accelerated registration which we call "generic registration." The pharmaceutical industry appears to have prospered. Research and development funds have increased year after year.

In fact, the amount of generic applications rose from 470 in 1984 to 1,069 in 1985, an increase of 127.45 percent. Of these 1,069 applications, 389 were approved. In 1986, there were 1,062 generic applications, but 616 were approved. This trend is expected to continue.

The new drug laws allow companies to make generic versions of off patent brand name drugs if they can prove to the FDA that their versions are equivalent to the brand name products. The requirement to repeat the studies to prove the safety and efficacy of established pharmaceutical compounds is no longer required. These new rules have created a new wave of the future for the pharmaceutical industry; Ciba Geigy, Smith Cline, American Cyanimid's Lederle Laboratories, Glaxo and Hoechst have all jumped into the generics marketplace because this is the place for future growth. (Ciba Geigy, American Cyanimid and Hoechst are also pesticide manufacturers and members of NACA).

Will the major agricultural chemical companies stop researching and developing new products if generic pesticide registration passes? Will they slash their R&D budgets by $100 million per year over the next several years? We think not!

The tax laws provide major incentives for research and development through favorable deductions and tax credits. A large amount of the cost of research and development is the cost of personnel. Salaries, bonuses and the expenses for R&D personnel may be written off under the tax laws in the year in which costs are incurred. Similarly, materials used in R&D may be written off in that year. These write-offs are all R&D costs, not just for costs of commercialized products. The costs of facilities where R&D is performed are capitalized and written off against taxes over several years.

Using generally accepted accounting practices, the costs of R&D is usually written off in the year the costs were incurred, up to 50 percent. There is also an R&D tax credit which provides another 25 percent write-off up front. This could mean that 75 percent of the cost of data is paid for by the American taxpayer.

A central argument raised in favor of patent term extension is that innovation is declining under existing law. The amount being spent on research and development is not declining. The U.S. chemical industry (including, but not limited to, pesticides and other farm chemicals) boasted profits of $4.25 billion in 1986, an 8 percent increase over the previous year. Other companies in the Business Week (June 22, 1987, pp. 144-145) survey reported profits as high as 15 percent above 1985 profit levels.

Another gauge of the state of the chemical industry is R&D expenditures for the year. The average annual R&D expenditure was 6 percent higher in 1986 than it was in 1985, with some companies posting R&D expenditures as high as 11 and 14 percent above 1985 levels, according to Business Week. The chemical industry appears to have no need to worry about a potential decrease in R&D following the implentation of generic registration, given these figures.

Also, chemical companies are pouring a considerable percentage of their profits back into R&D. In fact, the industry reported that an average of 48.6 percent of its pretax earnings went directly into its R&D facilities during 1986. That's right, nearly one-half of the nation's chemical industry's profits went directly into research for creating new chemicals, chemicals that will benefit U.S. consumers and farmers. Some members of the chemical industry reported even higher figures. One company in the Business Week survey reported that 95.9 percent of its pretax earnings were recycled to its R&D facilities. Do these figures reflect an industry were R&D is "drying up?" We think not.

CHEMICAL INDUSTRY
PROFITS AND RESEARCH AND DEVELOPMENT

Company	Profits		R&D		
	1986 (millions of dollars)	Percent annual change (1982-86)	1986 (millions of dollars)	% change from 1985	% of pretax profits
American Cyanamid	202.5	7	278.3	11	95.9
Dow Chemical	741.0	5	605.0	11	48.9
Du Pont	1538.0	11	1156.0	1	38.7
Ethyl	177.7	15	47.1	1	16.2
Great Lakes Chemical	26.8	12	13.2	9	30.9
Monsanto	433.0	7	523.0	11	82.2
Pennwalt	51.9	3	45.0	14	54.4
Rohm & Haas	138.0	10	132.8	8	60.6
Industry composite	**4247.5**	**8**	**3662.2**	**6**	**48.6**

(Source: Business Week, June 22, 1987, pp. 144-145). See Appendix.

The National Agricultural Chemical Association (NACA) surveys for 1984 and 1985 also reveal significant increases in R&D, by as much as 39.3 percent in 1984 and 18.9 percent in

1985. We see no reason why the American agricultural chemical industry would cut back its R&D expenditures. In general, the R&D costs are usually recovered within a few years, if only because firms will not invest in products with low rates of returns.

	Total R&D expenditures (in billions)	Increase from previous year	Percentage increase
1985	$868.9	$138.3	18.9
1984	$730.6	$206.2	39.3
1983	$524.4		

(See Appendix VII and Appendix VIII).

We fully realize the importance of research and development for the pesticide industry and the need to generate new chemicals for future needs. Farmers, consumers and pesticide users depend on the development of new products to increase crop yield, protect against serious infestations and improve the quality of life for all Americans.

We support legislation (H.R. 2569 and S. 746) that is not intended to deprive basic manufacturers from recouping their R&D costs for both successful and unsuccessful products, as well as receiving an ample return on their investment.

If we combine a 17-year patent life with a five-year extension of the patent , 22 years in all, there ought to be sufficient incentive for innovation and adquate time to recoup all of the R&D costs.

The current law and the 1987 proposed amendments go to great lengths to protect the investment interests of the original manufacturer, but we have done nothing to advance the interests of the farmers, ranchers, users and consumers who would benefit from greater generic competition and lower prices.

It is time to resolve this long standing inequity.

Thank you.

R&D SCOREBOARD

4 AUTOMOTIVE PARTS, EQUIPMENT

COMPANY	SALES 1986 MILLIONS OF DOLLARS	SALES PERCENT CHANGE FROM 1985	SALES PERCENT ANNUAL CHANGE (1982-86)	PROFITS 1986 MILLIONS OF DOLLARS	PROFITS PERCENT ANNUAL CHANGE (1982-86)	R&D EXPENSES 1986 MILLIONS OF DOLLARS	R&D EXPENSES PERCENT CHANGE FROM 1985	R&D EXPENSES PERCENT OF SALES	R&D EXPENSES PERCENT OF PRETAX PROFITS	EMPLOYMENT R&D DOLLARS PER EMPLOYEE	EMPLOYMENT ANNUAL CHANGE IN EMPLOYMENT (1982-86)
INDUSTRY COMPOSITE	**14459.4**	**4**	**12**	**334.4**	**54**	**341.0**	**12**	**2.4**	**52.8**	**2110.2**	**6**
Champion Parts Rebuilders	110.0	9	4	0.6	-13	1.3	-1	1.2	120.9	542.0	1
Clark (J. L.) Mfg. (11)	150.6	-3	-1	17.4	9	1.3	4	0.9	4.1	793.5	-6
Clevite Industries	299.5	1	8	6.3	NA	4.6	-4	1.5	50.3	1101.0	NA
Cummins Engine	2303.7	7	11	-107.3	NA	87.5	25	3.8	NEG	3804.3	5
Dana	3695.1	-2	12	85.9	15	51.0	11	1.4	26.6	1378.4	6
Eagle-Picher Industries (11)	648.3	1	6	38.8	37	17.1	35	2.6	24.7	2194.6	3
Eaton	3811.6	4	13	137.6	11	134.1	9	3.5	60.9	3087.2	4
Echlin (8)	901.9	17	17	48.8	18	7.3	16	0.8	8.7	808.3	14
Equion (7)	58.4	26	188	2.8	NA	1.2	46	2.0	20.4	2142.9	NA
Hurco (10)	44.8	-3	13	-1.8	NA	1.6	-49	3.6	NEG	4874.6	-5
Modine Mfg. (3)	312.0	3	16	20.5	41	6.3	-2	2.0	16.2	1708.3	9
Raytech	113.5	1	-3	3.0	NA	3.3	-15	2.9	71.8	2068.8	NA
Sealed Power	665.8	7	17	28.5	5	11.4	8	1.7	22.8	1022.8	14
Smith (A. O.)	910.9	3	10	26.1	10	9.1	-2	0.9	16.4	898.3	4
Standard Products (6)	433.2	15	18	27.2	50	4.9	10	1.1	10.0	887.5	13

5 BUILDING MATERIALS

COMPANY	SALES 1986 MILLIONS OF DOLLARS	SALES PERCENT CHANGE FROM 1985	SALES PERCENT ANNUAL CHANGE (1982-86)	PROFITS 1986 MILLIONS OF DOLLARS	PROFITS PERCENT ANNUAL CHANGE (1982-86)	R&D EXPENSES 1986 MILLIONS OF DOLLARS	R&D EXPENSES PERCENT CHANGE FROM 1985	R&D EXPENSES PERCENT OF SALES	R&D EXPENSES PERCENT OF PRETAX PROFITS	EMPLOYMENT R&D DOLLARS PER EMPLOYEE	EMPLOYMENT ANNUAL CHANGE IN EMPLOYMENT (1982-86)
INDUSTRY COMPOSITE	**13723.0**	**7**	**10**	**874.1**	**29**	**223.0**	**8**	**1.6**	**20.4**	**2072.7**	**8**
Ameron (11)	314.7	3	5	13.0	3	3.6	-22	1.1	21.2	1205.7	NA
Bird	184.4	-4	-8	0.4	NA	1.2	-21	0.7	143.8	1004.1	-15
De Soto	413.8	2	7	3.9	-26	22.1	7	5.4	287.2	8905.5	4
Guardsman Chemicals	97.8	2	9	3.9	42	3.8	2	3.9	51.7	4062.3	1
Lafarge	983.8	2	2	26.0	NA	4.9	4	0.5	8.4	844.8	-1
Lilly Industrial Coatings (11)	142.6	-2	9	8.5	18	8.0	3	5.6	47.9	6795.2	7
Manville	1920.3	2	4	81.2	NA	36.8	13	1.9	25.0	1845.4	NA
Moore (Benjamin)	352.5	10	12	25.5	18	4.4	16	1.2	8.3	2424.4	NA
Owens-Corning Fiberglas	3644.4	10	11	15.6	-8	63.0	5	1.7	229.7	2626.9	4
Pratt & Lambert	193.9	5	8	8.2	15	3.8	8	2.0	25.5	2365.4	5
Preway	112.8	-13	38	-12.3	NA	1.1	-28	1.0	NEG	1066.0	17
Sherwin-Williams	1552.9	2	4	98.0	28	12.3	11	0.8	7.1	898.7	-1
Sikes (2)	87.7	10	20	4.3	39	1.0	60	1.1	12.2	801.8	13
Stanadyne	492.8	2	10	21.1	12	11.8	-2	2.4	27.7	2327.4	3
Trus Joist	179.9	36	28	8.4	11	2.6	40	1.5	16.7	1261.2	20
USG	2723.7	17	28	255.4	65	29.7	30	1.1	5.8	1322.0	14
Valspar (10)	345.2	-1	27	14.8	17	14.8	-4	4.3	55.7	7015.8	19

6 CHEMICALS

COMPANY	SALES 1986 MILLIONS OF DOLLARS	SALES PERCENT CHANGE FROM 1985	SALES PERCENT ANNUAL CHANGE (1982-86)	PROFITS 1986 MILLIONS OF DOLLARS	PROFITS PERCENT ANNUAL CHANGE (1982-86)	R&D EXPENSES 1986 MILLIONS OF DOLLARS	R&D EXPENSES PERCENT CHANGE FROM 1985	R&D EXPENSES PERCENT OF SALES	R&D EXPENSES PERCENT OF PRETAX PROFITS	EMPLOYMENT R&D DOLLARS PER EMPLOYEE	EMPLOYMENT ANNUAL CHANGE IN EMPLOYMENT (1982-86)
INDUSTRY COMPOSITE	**89797.0**	**0**	**2**	**4247.5**	**8**	**3682.2**	**6**	**4.1**	**48.6**	**6092.7**	**-1**
Air Products & Chemicals (9)	1982.1	8	6	4.7	-44	61.1	20	3.1	805.0	NA	NA
American Cyanamid	3815.9	8	5	202.5	7	278.3	11	7.3	96.8	8075.6	-4
Betz Laboratories	344.4	8	8	35.5	4	13.1	9	3.8	19.6	4928.3	4
Crompton & Knowles	213.2	9	6	8.9	21	4.4	-4	2.1	27.3	3360.0	NA
Detrex	94.2	7	8	2.5	-6	2.6	60	2.8	55.5	3543.1	9
Dexter	650.1	3	5	33.6	6	27.6	7	4.2	46.6	5015.1	0
Dow Chemical	11113.0	6	2	741.0	5	605.0	11	5.4	48.9	11804.9	-2
Du Pont	27148.0	-8	-1	1538.0	11	1156.0	1	4.3	38.7	8183.0	-4
Ecolab (6)	612.9	12	6	43.7	8	10.9	53	1.3	15.0	1479.8	2
Engelhard	2289.5	1	3	53.3	-9	26.0	13	1.1	30.5	3788.1	-1
Essex Chemical	205.6	8	11	8.8	7	6.6	58	3.2	45.6	6562.4	NA
Ethyl	1579.3	2	-2	177.7	15	47.1	1	3.0	16.2	4481.4	-6
Ferro	725.2	11	5	24.1	10	11.7	8	1.6	26.0	1490.8	-2
First Mississippi (6)	268.9	-2	7	-28.1	NA	5.2	63	1.9	NEG	7809.1	NA
Fuller (H. B.) (11)	528.5	15	12	18.9	15	10.6	12	2.0	31.3	2356.9	3
GAF	753.8	3	4	80.7	60	11.4	10	1.5	9.1	2882.4	0
Grace (W. R.)	3725.7	5	1	-375.4	NA	94.2	6	2.5	NEG	2275.4	NA
Great American Management (7)	499.2	105	65	-3.7	NA	1.7	183	0.3	79.5	331.4	NA
Great Lakes Chemical	300.3	8	14	26.8	12	13.2	9	4.4	30.9	9992.3	12
Grow Group (6)	368.2	33	14	10.1	17	5.8	-11	1.6	29.5	1807.7	NA
Hercules	2615.1	1	0	226.7	15	71.1	-7	2.7	23.1	2832.1	1
HIMONT (10)	980.9	8	NA	97.3	NA	16.0	14	1.6	9.0	5713.9	NA
International Minerals & Chemical (6)	1177.7	-7	1	-79.6	NA	33.2	44	2.8	NEG	2388.5	11
Koppers	1398.4	0	5	63.2	NA	16.7	3	1.2	16.4	1530.2	-11
Lawter International	103.5	7	6	12.9	5	2.3	9	2.2	11.1	6248.6	4
LeaRonal (2)	105.0	-20	-10	6.0	-3	1.7	7	1.6	16.4	5076.9	7
Liquid Air	570.6	5	7	34.7	8	5.7	5	1.0	10.1	1292.9	3
Loctite (6)	266.8	15	5	23.2	10	10.1	15	3.8	29.5	3772.9	2
Lubrizol	985.2	8	5	78.2	10	51.2	18	5.2	39.8	10867.0	4
MacDermid (3)	86.3	-9	12	3.8	7	4.2	20	4.9	60.1	6483.1	6
Monsanto	6879.0	2	2	433.0	7	523.0	11	7.6	82.2	10115.5	1
Morton Thiokol (6)	1949.9	6	34	132.9	39	37.7	12	1.9	16.7	2108.1	27

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R&D SCOREBOARD

COMPANY	SALES			PROFITS		R&D EXPENSES				EMPLOYMENT	
	1986 MILLIONS OF DOLLARS	PERCENT CHANGE FROM 1985	PERCENT ANNUAL CHANGE (1982-86)	1986 MILLIONS OF DOLLARS	PERCENT ANNUAL CHANGE (1982-86)	1986 MILLIONS OF DOLLARS	PERCENT CHANGE FROM 1985	PERCENT OF SALES	PERCENT OF PRETAX PROFITS	R&D DOLLARS PER EMPLOYEE	ANNUAL CHANGE IN EMPLOYMENT (1982-86)
Nalco Chemical	736.1	3	5	63.7	2	33.2	4	4.5	29.2	6825.8	2
Oil Dri Corp. of America (7)	52.8	14	12	4.6	48	0.6	16	1.2	9.9	1382.2	6
Olin	1707.3	-3	2	75.2	17	56.0	5	3.2	48.7	4244.1	-2
Pennwalt	1107.6	8	6	51.9	3	46.0	14	4.1	64.4	4092.2	NA
Petrolite (10)	280.0	-9	-1	17.5	-10	12.1	-2	4.3	43.0	5642.3	NA
Products Research & Chemical (9)	92.0	10	12	7.3	21	5.3	16	5.7	41.3	7196.6	NA
Quaker Chemical	128.1	4	8	8.5	16	7.0	24	5.5	49.3	7565.1	0
Reichhold Chemicals	788.6	-7	0	15.9	26	14.0	11	1.8	47.8	3637.1	-2
Rohm & Haas	2087.0	1	3	138.0	10	132.8	6	6.4	60.8	11010.0	1
Sequa	371.4	14	10	28.1	22	11.3	38	3.0	39.3	718.8	NA
Stepan	259.8	10	6	7.5	6	9.5	15	3.6	67.4	9966.3	1
Union Carbide	6343.0	-1	0	130.0	NA	148.0	-10	2.3	65.5	2942.8	-4
Witco	1355.0	-6	1	65.2	18	21.9	4	1.6	20.2	2734.4	0
7 CONGLOMERATES											
INDUSTRY COMPOSITE	**52113.6**	**11**	**15**	**-843.7**	**10**	**1304.2**	**12**	**2.6**	**140.9**	**2187.1**	**13**
Allied-Signal	11794.0	29	20	605.0	19	459.0	34	3.9	50.6	3345.5	34
Colt Industries	1616.3	2	7	89.3	5	31.6	16	2.0	20.5	1716.6	0
Figgie International	919.8	14	9	42.4	13	15.7	11	1.7	19.3	965.7	8
ITT	7595.5	16	NA	527.9	NA	208.0	-12	2.7	18.2	1691.1	NA
Kidde	2356.2	9	6	52.2	3	21.3	33	0.9	23.3	560.5	NA
LTV	7271.4	-11	15	-3251.6	NA	19.5	-13	0.3	NEG	403.7	14
Rockwell International (9)	12295.7	8	15	611.2	16	407.5	11	3.3	38.5	3382.4	6
Teledyne	3241.4	0	3	238.3	3	84.6	-11	2.6	24.9	1888.4	1
Textron	5023.3	24	29	241.6	42	107.0	26	2.1	24.1	1486.1	15
8 CONTAINERS											
INDUSTRY COMPOSITE	**1191.7**	**-2**	**6**	**65.4**	**17**	**19.4**	**3**	**1.6**	**15.7**	**1878.6**	**NA**
Ball	1070.3	-3	6	58.9	14	17.0	2	1.6	15.4	1888.9	-1
Sealright	121.4	8	9	6.5	52	2.4	9	2.0	18.0	1809.1	NA
9 DRUGS ETHICAL, PROPRIETARY, MEDICAL & HOSPITAL SUPPLIES											
INDUSTRY COMPOSITE	**60549.5**	**19**	**8**	**6311.6**	**9**	**4721.0**	**17**	**7.8**	**40.4**	**8171.0**	**1**
A. L. Laboratories	121.7	29	54	5.5	99	3.1	33	2.5	20.0	2904.8	1
Abbott Laboratories	3807.8	13	9	540.5	17	284.9	18	7.5	34.8	7968.1	2
ALZA	51.6	27	26	9.0	30	19.4	34	37.6	106.5	NA	NA
American Home Products	4926.5	5	5	778.8	10	227.1	5	4.6	18.2	5221.4	-2
Bard (C. R.)	548.0	19	12	51.2	18	19.2	25	3.5	22.9	2666.7	4
Baxter Travenol Laboratories	5543.0	138	30	181.0	-5	203.0	62	3.7	78.1	3295.5	22
Becton, Dickinson (9)	1311.6	15	4	111.9	18	70.6	18	5.4	40.9	3657.4	-3
Biocraft Laboratories (3)	42.9	26	29	6.2	105	1.8	130	4.3	15.8	7973.9	NA
Bolar Pharmaceutical	55.2	44	29	10.0	27	4.6	15	8.3	25.0	18300.0	16
Bristol-Myers	4835.9	9	7	589.5	14	311.1	14	6.4	33.4	8914.0	NA
Carter-Wallace (3)	400.2	15	11	27.6	21	25.7	12	6.4	56.0	6618.3	4
Cetus (6)	39.6	-13	31	1.1	-22	6.0	-19	15.1	400.4	9501.6	6
Cooper Development (10)	174.2	104	53	-61.7	NA	17.7	74	10.2	NEG	3884.0	84
E-Z-EM (5)	47.5	22	13	6.9	28	1.7	33	3.6	16.7	2730.2	11
Forest Laboratories (3)	39.7	49	20	6.6	31	3.1	5	7.7	37.1	6073.6	NA
Genentech	127.3	56	44	-352.2	NA	32.2	39	25.3	NEG	27568.5	28
ICN Biomedicals (11)	41.1	155	50	3.1	43	0.8	10	1.9	13.5	1773.5	NA
ICN Pharmaceuticals (11)	102.8	64	28	9.4	34	6.2	32	6.0	31.3	3845.0	28
Johnson & Johnson	7002.9	9	5	329.5	-7	521.3	11	7.4	133.4	6761.3	-1
Life Technologies	98.3	17	19	3.7	17	7.4	25	7.6	109.0	6281.7	NA
Lilly (Eli)	3720.4	14	5	558.2	8	427.0	15	11.5	48.7	14673.5	-1
LyphoMed	129.3	89	90	15.7	96	4.8	97	3.7	16.7	3871.5	69
Marion Laboratories (6)	399.3	35	27	55.0	58	52.8	24	13.2	55.4	20574.6	11
Merck	4128.9	16	7	675.7	12	479.8	13	11.6	43.7	15628.7	-1
Mylan Laboratories (3)	80.8	51	27	20.7	60	4.1	34	5.0	10.8	13100.0	7
Par Pharmaceutical (9)	39.4	65	53	4.6	69	2.8	52	7.2	33.9	5438.5	NA
Pfizer	4476.0	11	6	660.0	17	335.5	17	7.5	34.8	8387.5	-1
Robins (A. H.)	789.9	12	13	81.6	12	51.8	-1	6.6	33.5	8100.8	3
Rorer Group	844.6	150	26	3.5	-33	69.7	206	8.3	465.4	9235.8	NA
Scherer (R. P.) (3)	185.6	11	2	-10.6	NA	4.9	31	2.7	187.0	1993.9	5
Schering-Plough	2398.7	15	7	265.8	7	212.1	12	8.8	56.7	9025.5	-3
SmithKline Beckman	3745.4	15	9	521.1	3	370.9	22	10.1	52.2	11168.4	3
Squibb	1784.6	27	11	263.6	20	163.0	17	9.1	43.2	9639.1	-
Sterling Drug	1990.4	14	4	171.5	8	102.9	21	5.2	34.3	4654.4	-3
Syncor International (5)	93.6	151	43	1.4	NA	1.2	-9	1.3	58.4	920.4	NA
Syntex (7)	980.0	15	8	207.6	10	143.0	17	14.6	58.9	15546.1	1
Upjohn	2291.4	14	9	252.6	12	314.1	11	13.7	87.7	15174.6	2
Warner-Lambert	3102.9	-3	-1	309.5	15	202.3	-3	6.5	45.4	6524.3	-7
Zenith Laboratories	50.4	-37	22	-4.1	NA	5.4	90	10.6	NEG	11654.3	17

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R&D SCOREBOARD

COMPANY	SALES			PROFITS		R&D EXPENSES				EMPLOYMENT	
	1986 MILLIONS OF DOLLARS	PERCENT CHANGE FROM 1985	PERCENT ANNUAL CHANGE (1982-86)	1986 MILLIONS OF DOLLARS	PERCENT ANNUAL CHANGE (1982-86)	1986 MILLIONS OF DOLLARS	PERCENT CHANGE FROM 1985	PERCENT OF SALES	PERCENT OF PRETAX PROFITS	R&D DOLLARS PER EMPLOYEE	ANNUAL CHANGE IN EMPLOYMENT (1982-86)
10 ELECTRICAL											
INDUSTRY COMPOSITE	**57210.9**	**16**	**6**	**3758.9**	**9**	**1864.0**	**16**	**3.3**	**33.4**	**2984.2**	**-1**
Acme Electric (6)	69.3	-8	6	1.9	29	5.0	9	7.2	148.0	5360.2	NA
Ametek	568.5	13	7	36.6	7	22.6	27	4.0	41.5	3587.3	4
Baldor Electric	181.7	4	6	6.9	-3	5.5	6	3.0	43.0	2340.4	1
Champion Spark Plug	883.8	7	3	-17.2	NA	16.0	3	1.8	NEG	1290.3	0
Cherry (2)	129.3	2	12	-2.3	NA	4.0	42	3.7	NEG	1640.9	8
Conrac	153.9	2	6	7.8	5	8.4	-7	5.4	54.5	6968.3	-13
Dual Lite (6)	38.9	4	0	3.5	83	0.5	-26	1.3	10.6	1136.9	NA
Duro-Test (7)	68.3	0	4	3.9	0	2.1	24	3.1	27.8	1235.3	0
Eldec (3)	84.8	23	8	4.7	-2	4.0	-35	4.8	50.7	2768.0	NA
Emerson Electric (9)	4952.9	7	9	408.9	8	151.7	8	3.1	21.2	2499.2	4
First City Industries	471.1	3	86	-13.8	NA	5.7	-11	1.2	NEG	671.0	NA
Franklin Electric	130.5	-27	-1	5.5	40	1.6	-24	1.2	17.3	820.9	-8
General Electric	35211.0	26	7	2492.0	8	1300.0	22	3.7	35.2	3621.2	0
High Voltage Engineering	98.0	17	6	4.6	20	1.5	1	1.6	18.0	1019.1	NA
Joslyn	149.5	-7	3	10.8	-6	1.3	0	0.9	7.0	787.9	-4
Kuhlman	147.5	-4	13	0.2	-41	3.5	42	2.3	NEG	2387.9	5
Lincoln Electric	370.2	-1	2	15.8	-4	10.8	18	2.9	36.6	NA	NA
MagneTek (6)	273.0	40	NA	4.4	NA	3.3	53	1.2	37.0	556.0	NA
Powell Industries (10)	78.7	20	7	-0.6	NA	1.7	39	2.2	NEG	2922.3	NA
R T E	330.1	-1	10	11.4	19	8.0	106	2.4	42.0	2659.3	5
Robbins & Myers (6)	95.7	-17	1	-7.4	NA	2.1	7	2.1	NEG	1484.5	-15
Slater Electric (11)	45.7	3	6	0.5	-25	0.8	-1	1.7	77.2	1098.7	0
Square D	1403.5	4	9	98.9	11	41.8	1	3.0	23.8	2036.8	NA
Superior Electric	52.1	5	5	-4.5	NA	5.0	62	9.7	NEG	6188.0	-3
TII Industries (6)	38.3	22	14	1.3	-27	1.7	21	4.5	135.0	1906.7	14
Thomas Industries	296.2	1	14	12.8	18	5.7	12	1.9	23.5	1875.0	4
Vernitron	93.3	-6	4	-1.1	NA	1.3	-28	1.4	NEG	836.9	NA
Westinghouse Electric	10731.0	0	3	670.8	12	246.0	0	2.3	30.7	2097.8	-5
Woodhead Industries (9)	63.9	7	7	2.8	-3	1.6	4	2.5	34.4	1954.2	7
11 ELECTRONICS											
INDUSTRY COMPOSITE	**69311.3**	**8**	**9**	**1622.0**	**-3**	**2586.3**	**5**	**4.4**	**93.8**	**3237.3**	**2**
ADT	508.7	8	6	22.3	-7	6.2	-25	1.2	16.2	672.8	1
AEL Industries (2)	104.9	25	23	4.7	65	2.1	132	2.0	31.6	1439.4	NA
AMP	1933.1	18	10	164.3	2	170.0	6	8.8	57.8	7798.2	3
AVX	195.4	9	11	-3.1	NA	5.5	-15	2.8	NEG	1078.4	5
ADAC Laboratories (9)	46.6	-18	-5	-22.0	NA	5.2	-27	11.1	NEG	16118.0	-20
Adams-Russell Electronics (9)	113.1	26	18	6.7	10	6.4	22	5.7	58.1	3658.9	NA
Andrew (9)	197.7	-8	9	9.5	-10	13.3	-17	6.7	81.3	5705.3	5
ARGOSystems (6)	79.5	22	28	5.2	28	3.4	16	4.3	34.7	3362.4	23
Augat	260.4	2	6	-8.7	NA	16.7	-2	6.4	NEG	4513.5	2
Avantek	208.2	24	28	16.1	18	25.4	25	12.2	86.4	8179.3	15
Aydin	136.8	3	1	7.0	-20	7.6	0	5.5	62.4	3793.5	0
Base Ten Systems (10)	37.3	18	22	0.8	-17	4.3	47	11.5	297.5	7274.1	NA
Birdview Satellite Communications (3)	58.9	7	71	-9.8	NA	1.5	12	2.6	NEG	NA	NA
Burndy	242.1	11	2	9.5	-10	9.4	4	3.9	49.5	2452.3	0
CTS	245.5	-6	5	-26.6	NA	7.2	-29	2.9	NEG	1105.3	1
California Microwave (6)	104.4	-1	4	4.4	0	3.4	1	3.3	43.5	3620.5	-3
Checkpoint Systems	35.6	31	33	6.2	47	1.8	67	5.1	25.1	4002.2	16
Chyron (6)	35.6	21	30	2.3	-10	3.6	1	10.1	91.3	8323.3	38
Cincinnati Microwave	102.1	-9	NA	11.5	NA	2.2	51	2.2	9.9	4171.7	NA
Combustion Engineering	2551.5	6	2	56.3	-8	48.0	-20	1.9	46.8	1988.7	-4
CompuDyne	71.1	15	12	1.9	-22	1.5	30	2.1	38.4	1409.8	NA
Cordis (6)	188.1	-5	10	-2.9	NA	27.7	8	14.7	NEG	8888.1	NA
Cubic (9)	337.8	2	5	1.1	-42	5.8	27	1.7	689.1	1287.5	5
DBA Systems (6)	74.4	13	36	4.2	34	1.1	2	1.5	17.0	1422.4	27
Data Design Laboratories (6)	67.4	-31	2	0.4	NA	0.8	-58	1.1	NEG	758.0	NA
Datascope (6)	67.4	33	20	3.0	10	4.3	4	6.4	86.7	5497.5	10
Diagnostic/Retrieval Systems (3)	36.0	6	20	0.8	-23	2.6	4	7.2	435.4	6536.7	21
EDO	113.2	-3	3	6.3	-5	3.1	-3	2.8	26.4	2094.2	1
EECO	62.6	15	17	2.4	31	3.0	-12	4.8	67.4	3384.1	6
EG&G	1145.1	-1	10	44.9	4	16.4	-2	1.4	22.7	713.0	NA
Electro-Biology	36.9	10	14	2.7	2	4.0	-15	10.7	119.1	12771.0	6
Electro Scientific Industries (5)	70.6	-16	22	1.9	21	8.3	12	11.8	422.7	9257.8	12
Electromagnetic Sciences	48.0	44	34	5.5	35	1.6	16	3.3	15.3	2136.0	NA
Electrospace Systems (3)	145.0	35	28	13.4	32	3.4	60	2.4	14.8	1689.9	23
Equatorial Communications	50.9	-9	56	-67.8	NA	4.9	42	9.6	NEG	12401.5	57
FONAR (6)	36.7	334	385	1.4	NA	3.6	27	9.9	143.4	12360.5	42
General DataComm Industries (9)	178.0	-3	34	3.9	3	19.6	16	11.0	1323.5	7564.2	24
General Instrument (2)	787.9	29	2	18.5	-34	52.9	14	6.7	178.2	3245.9	NA
Harman Intl. Industries (6)	228.3	28	14	8.6	91	5.8	44	2.6	44.7	2718.6	NA
Harmon Industries	47.2	-11	18	2.1	18	2.4	13	5.0	57.0	3057.0	10

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Prepared Statement of Warren E. Stickle, Executive Director, Chemical Producers & Distributors Association

Mr. Chairman, my name is Warren E. Stickle. I am Executive Director of the Chemical Producers and Distributors Association. We thank you for this opportunity to discuss our position on the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the need for generic pesticide registration.

The Chemical Producers and Distributors Association (CPDA) is a voluntary non-profit membership association consisting of about fifty companies engaged in the manufacture, formulation, distribution and sale of products used on food, feed and fiber crops and for lawn and garden care. We are primarily composed of small- to medium-sized businesses engaged in the formulation, manufacture and distribution of some $2 billion worth of agricultural pesticides.

A majority of our members rely upon the production of "generic" pesticides, those products on which the patent has expired. Our membership provides a much needed service to the agricultural community in formulating and distributing those chemical tools necessary to allow all of us to enjoy an abundance of agricultural products at a fair and competitive price.

Today, I am accompanied by Mr. Robert D. Shockey, Chairman of the Board of Chapman Chemical Company, Memphis, Tennessee, and President of the Chemical Producers and Distributors Association; Mr. Jimmy Whatley, Director, Corporate Research and Development, the Griffin Corporation, Valdosta, Georgia; and Mr. Richard Miller, Executive Vice President, Prentiss Drug and Chemical Company, Floral Park, New York.

Mr. Shockey will briefly discuss our support for Congressman Charles Hatchers' legislation (H.R. 2569) on generic pesticide registration. Mr. Whatley will discuss some of the current problems with the data compensation and arbitration system in FIFRA. Mr. Miller will discuss the impact of these actions on R&D and innovation in the pesticide industry.

The Pesticide Price Competition Act:

Mr. Chairman, we at CPDA strongly support H.R. 2569, the Pesticide Price Competition Act, a bill introduced by Congressman Charles Hatcher (D-Ga.). We commend Congressman Hatcher for his leadership on pesticide issues facing this Congress, especially the need to lower pesticide prices for farmers, ranchers, users and consumers, while increasing competition within the pesticide industry, especially for small businesses. An identical bill, S. 746, has been introduced on the Senate side by Senators Nancy Kassebaum (R-Kan.) and Al Gore (D-Tenn.)

H.R. 2569 would establish an abbreviated generic pesticide registration system, stimulate competition in the pesticide industry and lower the price of pesticides for farmers, ranchers, users and consumers.

The purpose of this legislation is to lower the farmer's cost of production by reducing the costs of pesticides that farmers buy each year and reduce the cost of non-agricultural products that consumers buy in their grocery and hardware stores. This measure could save farmers from $400 million to $500 million per year for at least the next five years on agricultural pesticides alone. Consumers could save additional millions on non-agricultural products.

It appears the Administration also generally approves this approach. In a letter dated March 10, 1986, Health and Human Services Secretary Otis Bowen wrote to Senator Strom Thurmond (R-S.C.) about restoring patent time lost due to federal premarket requirements for veterinary drugs, pesticides and agricultural chemicals. "In summary," wrote Secretary Bowen, "we support patent restoration for veterinary drugs, but urge the Congress to add an additional provision that would enable manufacturers to obtain federal premarket approval to market generic versions of these drugs without having to duplicate the potentially costly and time-consuming safety and effectiveness studies that are required of manufacturers...without such a provision, there would appear to be no need for patent restoration since the current federal requirement for duplicative testing would continue to serve as an effective economic barrier to competition even after the expiration of patents that would be restored by this legislation," concluded Secretary Bowen.

"Patent restoration would have little meaning, however, if federal regulatory barriers had the effect of preventing the marketing of virtually identical generic products after patents expire," Bowen observed. "We have concluded," Bowen pointed out, "therefore, that both patent restoration and an abbreviated approval procedure ought to be included in the same legislation so that they may be considered and, hopefully, enacted together."

Secretary Bowen noted: "We continue to believe that it is good public policy to link the two concepts in order to foster research for new products and, at the same time, encourage competition and lower prices. In our view, it would be unfair to consumers as well as to the industry as a whole if one were enacted but not the other, or if a substantial time lag occurred between the enactment of both." Mr. Chairman, I ask unanimous consent that the full text of Secretary Bowen's letter appear in the Record following my remarks. See Appendix X.

As we look across our land, we discover an agricultural and rural economy suffering from problems--increasing costs of production, growing debts, more problems obtaining adequate credit, declining prices for crops--and we need to move forward to address these concerns. One way to help the farmer address the increasing costs of production is to face the problems head-on. By amending the pesticide legislation, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), it is clearly possible--even desirable--to increase competition in the pesticide industry, resulting in reduced pesticide prices and lowering the farmer's cost of production, without costing the government a penny!

Should we give farmers a break? Should we join together to reduce the cost of pesticides for our farm community? Should we seek to lower the farmer's cost of production? Is it time that the Congress act to alleviate some of the economic distress facing rural America?

Increased Competition Will Reduce Pesticide Prices:

Farmers across this country apply agricultural pesticides to their crops and these costs are a significant percentage of the cash variable expenses (seed, fertilizer, chemicals, hired labor, etc.) that farmers pay each year. According to the recent figures gathered by the *Economic Indicators of the Farm Sector, Cost of Production, 1985*, prepared by the United States Department of Agriculture, pesticides average between 10 and 35 percent of the cash variable expense. For soybeans, farmers spend $17.47 per acre for chemicals, equalling 32.3 percent of the cost of production. For peanuts, farmers nationwide spend about $80 per acre for agricultural chemicals or about 30 percent of their cost of production. For cotton, farmers spend $45 per acre or 21 percent of their cost of production for pesticides. For sugar cane, it is $56, and for rice it is about $27 per acre. For corn, it is about $18 per acre, or almost 9 percent of their cost of production. Farmers also apply significant amounts of pesticides for tobacco (burley - $70 and flue-cured - $94). For wheat, it is almost $3 per acre for agricultural chemicals. In essence, farmers spend a considerable amount of their cash reserves on pesticides.

In the southeastern section of the country, farmers face an even greater challenge. While cotton farmers across the nation average $45 per acre for chemicals, farmers in the southeast apply $96 of pesticides per acre. Peanut farmers average about $80 per acre for chemicals, but southeastern peanut farmers average almost $95 per acre. Virginia and North Carolina farmers average almost $89 per acre. Southeastern farmers, like the Hawaiian sugar cane growers and Texas sugar beet producers, pay a disproportionate share of their cost of production for agricultural chemicals.

If we can encourage the development of generic pesticides, we can lower the prices of pesticides that farmers buy and reduce the farmer's cost of production. It may be possible to reduce the price of pesticides by 10 to 20 percent or more. For those crops like peanuts, cotton, rice, sugar cane and tobacco, we might be able to save farmers from $5 to $25 per acre in pesticide costs. For large acreage crops, like corn, soybeans and wheat, we might be able to save farmers almost $3.50, $3.50 an $.60 per acre respectively. Without doubt, however, we can help the farmer reduce the cost of production at a time when the cost of most items purchased by the farmer have been rising higher and higher. Please see Appendix I.

One way to reduce these costs is to amend the data compensation issue of FIFRA. When generic pesticide producers enter the market following the expiration of a patent, they generally capture only 10 to 20 percent of the existing market. (Ciba-Geigy sells more triazine products in pounds now than when the patent expired eleven years ago.) With the fear of losing more of a market share, the overall impact on reduction in prices can be significant.

Generic Pesticides Lead to Price Declines in the 1970s:

In April 1977, Donald I. Baker, Assistant Attorney General, Antitrust Division, U.S. Department of Justice, wrote to a member of Congress and reviewed the impact that patent expiration had on prices. "Prior to the 1972 amendments," wrote Baker to former Congressman Floyd Fithian (D-Ind.), "when generic producers could economically manufacture technical pesticides upon expiration of the patent, prices typically dropped dramatically upon patent expiration (emphasis added)." Baker further concluded:

> "For example, the price per pound of DDT fell to about 1/4 of the pre-expiration price per pound when competition was introduced, suggesting that monopoly profits were quite significant (and likely adequate to cover registration costs.)"

During the 1970s, a major pesticide--atrazine, an 80 percent wettable powder (produced by Ciba Geigy)--was used by farmers to control weeds for corn and sorghum. During the early 1970s, the price of atrazine was essentially constant, with minor fluctuations. In 1977, the price dropped from $2.50-$2.75 a pound to about $2 per pound, a decrease of at least 20 percent. Other pesticides, according to the General Pesticide Index, were increasing by 8 percent in 1977. See Appendix II.

The decline in atrazine prices is attributable to the expiration of the patent in 1976. Robert Lee, Economic Analysis Branch, EPA, concluded:

> "With such a large share of the market in a major crop like corn, entry by additional firms is expected, resulting in a smaller share in the atrazine market for Ciba Geigy and further declines in price."

The national market for atrazine was about 100 million pounds in 1977. A drop in price of 50 cents per pound saved $50 million. For those farmers who used atrazine, there was a saving of $1.25 to $1.50 per acre. A farmer with 500 acres of corn saved $625 on his cost of atrazine. If the patent on atrazine had been extended for five years, farmers would have had to pay an additional $250 million in higher prices. See Appendix III.

In addition, Robert Lee further pointed out that following patent expiration, the price of maleic hydrazide--a growth retardant on tobacco, onions and potatoes--fell dramatically by 118 percent from the last year of patent protection to the first year without protection. He concluded that the decline in price "can be attributed to the expiration of its patent." This was due to both small domestic companies (Drexel, Cumberland, Fairmont) and imports starting a generic market.

During the 1970s, other products coming off patent experienced a decline in prices. Diuron (DuPont) and Simizine (Ciba Geigy) showed significant reductions. Diuron dropped from about $3.25 per pound to about $2.40 per pound, a drop of 85 cents per pound, or 26.2 percent. Simizine declined from $15.00-16.00 per gallon to $9.00-10.00 per gallon, a decline of about $6 per gallon or about 40 percent.

The 1970s provides a clear example when prices dropped after the patent expired, resulting in millions of dollars in savings for farmers, ranchers, users and consumers.

Another pattern also emerged during the 1970s. In 1977 and 1978 the basic manufacturers argued that they needed additional protection and asked Congress to enact a 10-year exclusive use period followed by a five-year period of compensation. In 1978, Congress passed legislation containing these provisions.

"It is curious," remarked Donald Baker of the Department of Justice, "that the asserted need for protection of the test data [1977] became evident only when significant numbers of pesticide patents began to run out. We find the disincentive argument somewhat disingenious."

During the 1970s, two patterns emerged: 1) prices declined after the expiration of the patent, thus benefitting farmers and consumers, and 2) the industry demand for protection occurred when patents were beginning to run out.

And these 1970s patterns have continued into the 1980s as well.

Generic Pesticides Lead to Price Declines in the 1980s:

During the 1980s, some major agricultural products came off patent and generic producers, with great difficulty, entered the marketplace, significantly reducing the price for consumers and farmers. The following chart clearly indicates that these three pesticide products have dropped an average of 18.1 percent.

Product Trade Name and Year Entered the Market

	Phostoxin (1982)	Treflan (1985)	Sutan (1984)
Pregeneric prices	30.20/kg.	28.50/gal.	19.89/gal.
(Prices after generics entered the market, '86)	24.28/kg.	21.43/gal.	17.90/gal.

Percent change in price	-19.6%	-24.8%	-10.0%

Average Price Decrease = 18.1%

When generic products enter the marketplace, pesticide prices decline. Many other agricultural chemicals, presently under patent, are, however, experiencing price increases. The following chart for three pesticides selected at random (and representative of products used in U.S. agriculture) shows that their average price increase was about 9.9 percent between 1983 and 1986.

	Product Trade Name		
Year	Furdan	Lasso	Lorsban
1983	$40.72/gal.	$17.73/gal.	$26.80/gal.
1984	46.69/gal.	18.59/gal.	30.21/gal.
1985	44.82/gal.	18.61/gal.	29.59/gal.
1986	45.77/gal.	18.06/gal.	30.93/gal.
Percent change in price	+12.4%	+1.9%	+15.4%

Average Price Increase + 9.9%

During the 1980s, we have witnessed a continuing pattern of price reductions when pesticide products have come off patent, while other pesticide prices have increased.

It is ironic that, in the period between 1984 and 1987, the basic manufacturers have begun another major effort to protect their monopolistic control of the marketplace by requesting Congress to enact patent term extension, an effort to recover up to five years of time lost in the regulatory process at EPA. It just happens that over the next five years (1987-1991) about 21 pesticides--some of the most widely used and most profitable--used by the American farmers will come off patent. These pesticides constitute about 45 percent of all pesticides used by farmers today.

Hard cost estimates are difficult to come by, but by analyzing past experiences when pesticides have finally been produced by generic manufacturers and also by comparing domestic price levels with the prices that major producers charge for their product overseas, it is clear that a vigorous competition in the pesticide industry would significantly lower the price of generic pesticides to farmers, possibly by as much as $2 billion over the next five years.

Congress has an opportunity to correct this inequity by amending the current law to provide for a reasonable compensation to be paid by generic producers.

As competition in any market develops, the price of the product generally declines. Currently, a farmer in Central or South America is paying a lower price for his pesticides than an American farmer. As an example, insecticides being used on cotton are selling for $1.00/lb. overseas and for $1.55/lb. in the U.S. An insecticide for the control of malarial mosquitoes sells for $.80 to $.85/lb. overseas and $1.60/lb. in the U.S.

Once a product comes off patent, its price can be expected to move closer to the world market price. The following list shows examples for U.S./foreign price differentials which exist now for several products. The U.S. price is expected to move toward the more competitive foreign price.

The following are products and comparison prices:

Product	U.S. Price	Foreign Price
Malathion	$1.55-1.65/lb.	$.82-.95/lb.
Methyl Parathion	$1.55/lb.	$.92-1.05/lb.
Carbaryl	$2.55/lb.	$1.85/lb. (Spain)
Treflan	$26.00/gal.	$16.00/gal.
Paraquat	$32.00-36.00/gal.	$13.00/gal.

There are also products that, while still patented, nonetheless exhibit a large price difference between U.S. and foreign markets since the patent is not enforced outside the U.S.:

Product	U.S. Price	Foreign Price
Roundup	$68.00/gal.	$42.00-44.00/gal.

Anticompetitiveness and Monopolistic Tendencies of the Pesticide Industry:

We are trying to increase competition in the pesticide industry by addressing business issues which have a direct impact upon the ability of our members to conduct business. Without changes in the data compensation area (generic pesticide registration, 3 (C) (1) (D) and 3 (C) (2) (B)), our members will be at a decided economic disadvantage due to these artificial barriers to generic products.

Studies have shown the anti-competitive nature of the pesticide industry (Eichers, 1980). There has been a redistribution of profits in favor of chemical producers and away from formulators and distributors (the percentage of each consumer dollar going to basic chemical producers increased from 45 percent in 1965 to 66 percent in 1976). There also appears to be increasing forward vertical integration in the pesticide industry. About 50 percent of all formulators are now controlled by basic producers through either direct ownership or contractual obligation (Eichers, 1980, p. 13).

Even when patents expire, new entry into the market may be difficult in some cases because generic producers must still register their version of the chemical with EPA. The EPA has attempted to reduce the time lag by using data submitted by the original registrant under 3 (C) (1) (D) of FIFRA. This action in turn has stimulated law suits brought by the original registrants who insist on receiving compensation for the data. Such legal action can insure that generic registrations are delayed in court for a lengthy period, effectively lengthening the life of a patent (Butler letter, March 20, 1986, to Senator Charles Mathias, Jr.).

The pesticide industry is highly concentrated with ten companies controlling 66 percent of the world pesticide market. The U.S. market had been maintained in a fairly competitive mode before 1978 due to the moderate rate of turnover of leading products, allowances for generic registrations under section 3 (C) (1) (D) of FIFRA and patent expiration. However, unreasonable data compensation decisions under section 3 (C) (1) (D) are reducing the number of new entrants into the market on non-patented pesticides. As competition in the market decreases, the incentive to be innovative also decreases, a generally recognized empirical result of most industrial organization studies.

Today, technology and data are protected under Section 10 of the present FIFRA law. The major companies would have you believe that technology is being exported by allowing the use of data for a generic registration when, in fact, technology and data are being imported into the United States.

The top ten agricultural chemical companies in the world are:

Company	Country	U.S. Name
Bayer	German	Mobay
Ciba Geigy	Swiss	Ciba Geigy
Monsanto	U.S.	Monsanto
Shell	U.S.	DuPont
ICI	British	ICI America
Rhone Poulenc	French	Rhone Poulenc
Dow	U.S.	Dow
Hoechst	German	American Hoechst
DuPont	U.S.	DuPont
BASF	German	BASF

The top three companies, Bayer, Ciba Geigy and Monsanto, account for 31 percent of the world pesticide sales. The next seven companies accounted for the next 35 percent of sales worldwide. These ten companies hold a total of 66 percent of the world's pesticide sales, seven of which are not American companies. Technology is actually coming from abroad.

These same ten companies are the largest importers of pesticides into the U.S. The NACA Industry Profile Study states that U.S. sales on non-U.S. production have remained about the same: $1,379 million in 1983, $1,366 million in 1984, and $1,318 million in 1985, or about 25 percent of U.S. production.

The Need to Adopt an Equitable Standard for Data Compensation:

FIFRA does allow an alternative to the manufacturers of generic pesticides if they wish to enter the market without replicating the data. In that event, the generic manufacturer must offer to pay compensation to the holder of the data (product is patent free) so that EPA may refer to that data in their files in considering an application for registration by a generic manufacturer. Section 3 of FIFRA, however, set no clear standard for the compensation that must be paid. Using general accounting practices, the data producer can write off the cost of data development in the year the cost is incurred, thus leaving the public financially responsible for the cost of the data. With the general public actually paying the cost of the production of the data, these data should be in the public domain, thereby allowing generic registration.

We need an amendment that explicitly and unambiguously confirms the Congressional intention that reasonable compensation for data under section 3 (c) (1) (D) of FIFRA should be fair and equitable.

When a company decides to enter a pesticide market, after the expiration of the patent, it must be able to determine all of its potential costs in order to make a sound business decision. It can define (1) the manufacturing process, (2) raw material costs, (3) cost of plant construction, (4) general overhead, and (5) potential market. While these times are sufficient in most businesses, there is one important element missing for a pesticide product: data compensation for the use of data submitted by another registrant to support the registration of your product.

On its face, FIFRA provides that, if a registrant relies upon data submitted by another registrant, he must offer to pay compensation to the original data submitter. The statute does not provide a definition of "reasonable compensation." If the parties involved cannot reach an agreement, then either one may request that the matter be submitted to binding arbitration before the Federal Mediation and Concilation Board which is to determine "reasonable compensation".

We believe the prior history of FIFRA makes it clear that this compensation is to reflect solely the original data submitter's production cost. However, the lack of an express standard in the statement has allowed considerable mischief. The only data compensation case which has been specifically decided by binding arbitration, to date, is Stauffer Chemical vs. PPG Industries, Inc. (Stauffer/PPG). The Stauffer/PPG case was heard before a panel of three arbitrators. The final decision against PPG provided for:

- PPG to pay 50 percent of the cost of the data relied upon by the EPA to register their product which had been submitted by Stauffer and was in the Agency's files. The data in question was valued at $2,930,000 and PPG was ordered to pay $1,465,000 to Stauffer within 30 days of the final decision (NOTE: The data which Stauffer had submitted is not sufficient to fully register the product under section 3 of FIFRA and will require PPG to possibly develop or replace several million dollars worth of data when the registration standard is finalized by the EPA).

- The arbitrators ruled that PPC had gained a market advantage by not having to wait the five to seven years necessary to develop the data themselves and obtain EPA registration. They also ruled that, since PPG had gained valuable time by relying upon Stauffer's data and having the benefit of their registered labels to copy. To compensate Stauffer for the market advantage PPG gained by relying upon Stauffer's data and labels, the arbitrators awarded them \$0.15 per pound of technical produced or purchased by PPG during the ten calendar years from 1983 through 1992. The price per pound is to be adjusted annually based on the change in the Producer Price Index using November 1982 as the base year.

It is important to note that the \$0.15 per pound awarded was determined by the arbitrators based upon a net profit by PPG of \$0.60 per pound of technical. This is equivalent to 25 percent of PPG's net profits. No allowance was made in the decision for a drop in the net profit to below tne projected \$0.60 per pound. If PPG's net profit dropped to \$0.30 per pound, they would then by paying Stauffer 50 percent of their net profits.

The cost of the actual arbitration process must also be considered. The fees charged by the three arbitrators and the American Arbitration Association (AAA) in the Stauffer/PPG case were \$96,000. Stauffer and PPG split this cost with each paying \$48,000. It is estimated that the legal fees for PPG in this matter would have been approximately \$300,000. The hearings lasted 20-22 days and the case was months in preparation. This estimate of PPG's costs in this matter does not include their in-house administrative costs.

Based upon the above figures and estimates for sales contained in the arbitration decision, PPG's initial costs for data compensation and arbitration were \$1,813,000 plus an additional \$7,087,500 in royalty payments during the first five years of sales. If PPG's sales remained stable during the ten-year period in which royalty payments are to be made, the total cost to PPG for data compensation would be approximately \$15,988,000 or 5.4 times the cost of the data involved. Is this decision fair and equitable? We think not!

Recently a second case has been submitted to the arbitrators by E.I. du Pont De Nemours & Co., Inc. against Griffin Corporation and Drexel Corporation. In this case, Du Pont is asking:

- $3,000,000 from each of the companies, or 25 percent of its estimated development cost for the data plus;
- a royalty of $1.50 per pound of pesticide sold containing linuron sold by the respondents during the first five years of sales.

As can be seen by the above two cases, it would be very difficult for a small company to decide to enter a market previously held by a major producer. The cost of such an arbitration award under the law would be out of reach of a small businessman. If he were successful in obtaining entry into a market, he could still be faced with future development of several million dollars worth of data when the registration standard for the product was issued, and when he was required to reregister his product.

We believe that a decision such as the Stauffer/PPG decision is totally outside of the intent of Congress when it passed the requirements for reasonable compensation in 1972, or when the statute was amended in 1975 and 1978. We believe the intent of this section was to allow a company which relied upon data submitted to the Agency by another registrant to share in the cost of development of that original data and not to reward the original registrant for being the first to register the pesticide product. We contend that such reward is the purpose of the patent laws and not FIFRA.

Reasonable compensation should be an equitable sharing of the costs of the data. In the opinion of Justice Sandra Day O'Conner written for the Supreme Court, Union Carbide vs. EPA case, Justice O'Conner cited legislative history on this point which we believe is controlling. The Court was not, therefore, called upon to squarely address this issue and did not. The present reauthorization gives the Congress a chance to now expressly clarify the compensation standard to the benefit of all, and we urge that you do so.

The Need to Repeal the Bolar/Roche Decision:

Current patent law allows the recipient of a pesticide patent an exclusive life of 17 years. Basic supplier companies have requested legislative changes to this law by asking that up to five additional years of patent life be added to the pesticide product. The intent of the legislation is to restore lost patent life resulting from the lengthy regulatory review period needed to obtain EPA approval. While a product is being reviewed, it cannot be marketed.

In addition to the anti-competitive nature of the present system of determining data compensation, a recent decision by the United States Court of Appeals has brought into question the practice of developing data necessary to support the registration of an identical pesticide product prior to the expiration of a patent.

On April 23, 1984, the United States Court of Appeals for the Federal Circuit handed down a decision in Roche Products, Inc. vs. Bolar Pharmaceutical Co., Inc. ruling that the use of a patented product by a second party to develop data for the purpose of obtaining an early market entry following the expiration of a patent was a violation of the "use" provisions of the law. The Court held that, while there was an exemption for the use of a product for scientific purposes, the exemption did not apply when the information gained was for commerical purposes. This decision prohibits the manufacturer of a generic pesticide from developing any data which would be necessary for the registration of one product prior to the expiration of its patent.

This court decision effectively adds a period of up to seven years to the term of a patent, in addition to the proposed five-year extension, totaling a patent life of 29 years if the bill should become law. This is shown in the following scenario:

....Regular patent, 17 years....17 years
....With patent term extension....22 years
....Bolar/Roche cost of time 5-7 years....29 years

In section 202 of the Drug Price Competition and Patent Term Restoration Act of 1984, provisions were included to overrule the Bolar/Roche decision. Essentially those provisions stated that it would not be an act of infringement to make, use or to sell a patented invention solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use or sale of drugs.

If a product is to receive patent extension, as originally proposed by H.R. 2482 and S. 2792 (99th Congress), or as proposed in H.R. 1345, introduced by Congressmen Frederick Boucher and Michael DeWine, there should be a full repeal of the Bolar/Roche decision. These legislative vehicles do not, however, contain a full repeal, but only a limited repeal for just two years. Such a limited repeal provides little benefit to generic manufacturers, especially if the testing and EPA review take five to seven years, leaving us with a three to five year deficiency. In addition, the Bolar/Roche decision does not allow the generic manufacturer to submit his test results for EPA review prior to the expiration of the patent. Congress wisely created the generic pharmaceutical industry following patent term restoration and we feel that such a move within the pesticide industry would benefit all users.

We at CPDA believe that a generic manufacturer in the pesticide industry should be on an equal footing with drug manufacturers and do the testing and file an application for registration before the expiration of a patent, as long as there is a prohibition against marketing before the patent expires.

These de facto circumstances created by Bolar/Roche clearly prohibit market entry, deny small businesses access to the market place and deprive farmers and consumers of lower priced pesticides.

An important point to remember when thinking about patents is that there can be multiple patents on a compound. A company in the pesticide field will first apply for a composition of matter patent, then a manufacturing patent, a third patent and possibly a fourth on the intermediates used to manufacture the compound. A use patent would be next and then a formulation patent would be requested. With five patents on one compound, separated by a few years, a company would essentially end up with a patent in perpetuity. Does anyone really need patent term restoration?

Importantly, all formulations of a pesticide containing the identical active ingredient should be considered the same pesticide, and no pesticide should be subject to more than one patent extension. In no event shall more than one patent be extended for the same regulatory review period for any product.

We recommend inclusion of an amendment to H.R. 2463 to redress the deficiencies of the Bolar/Roche decision, as outlined in Appendix IV. If this type of amendment is not included in H.R. 2463, there is no need for patent term restoration. In effect, the basic manufacturer of the pesticide ALREADY has an extension of the patent by virtue of the period of time required to replicate the test data and obtain an EPA registration prior to bringing the pesticide onto the market. Under the present circumstances, it is nearly impossible for a generic manufacturer to develop his own set of data.

Research and Development, Innovation and Greed?:

Research intensive chemical companies claim that they need the enactment of patent term restoration so they can increase innovation.

In 1986, the Committee for Research and Development of Agricultural Chemicals, composed of 11 basic manufacturers, warned the Congress:

> "If Congress amends the FIFRA to allow low-cost access to health and safety data for follow-on registrants,...private sector R&D in agrichemicals will decline by $100 million or more each year -- from a base of $553 million in 1985..."
> (See Appendix V, page 3).

The leaders of the agrichemical industry would have us believe that, in five or six years, research and development would almost diappear! Does anyone really believe this misleading rhetoric? Is the agrichemical industry crying wolf?

Are these misleading statements from the agrichemical industry leaders reminiscent of the statements issued by the drug manufacturers during the congressional debate in 1983-1984 about establishing generic drug registration? What did the Pharmaceutical Manufacturers Association (PMA) state on July 25, 1983? The following statements represent their views on R&D in 1983:

> "Innovation will dry up."
>
> "...it [H.R. 3605] nonetheless strives to reduce economic incentives for important pharmaceutical research still further."
>
> "But whatever short-term savings may be acheived will come at an enormous long-term cost to the public in terms of reduced pharmaceutical research, fewer new medicines in the future..."
>
> "H.R. 3605 would substantially reduce the attractiveness of investing in new drug research."1

But has R&D in the pharmaceutical industry dried up in the last few years or in the period since the passage of the generic drug bill? What are the facts?

Since 1984, there have been no declines in drug research and development funds, only increases--about 14 percent per year for 1985 and 1986!! In the past two years, an additional $1 billion has been poured into R&D. Research and development has actually doubled since 1981! And has doubled nearly every five years since 1961!!

	R&D Human & Veterinary (millions)	Percentage increase	Actual increase
1986	$4,647	13.95%	569,000,000
1985	$4,078	13.94%	499,000,000
1984	$3,579	10.86%	361,000,000
1983	$3,218	18.97%	444,000,000
1982	$2,774	18.00%	433,000,000
1981	$2,340	18.36	363,000,000

(See Appendix VI).

What about the dire prediction of innovation drying up? Of interest in R&D declining? Of reduced research? No longer do we hear these outlandish predictions of doom coming from the pharmaceutical industry.

1 Portion of statement of the Pharmaceutical Manufacturers Association (PMA) before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives, on H.R. 3605 on July 25, 1983.

In 1984, Congress provided the pharmaceutical industry with patent term restoration. This law contains not only the restoration of time lost to regulatory review, but also eliminated the Bolar/Roche decision, and provided accelerated registration which we call "generic registration." The pharmaceutical industry appears to have prospered. Research and development funds have increased year after year. Two hundred fifty-four Abbreviated New Drug Applications (ANDA) appeared at the FDA within the first days after enactment.

In fact, the amount of generic applications rose from 470 in 1984 to 1,069 in 1985, an increase of 127.45 percent. Of these 1,069 applications, 389 were approved. In 1986, there were 1,062 generic applications, but 616 were approved. The effect was delayed because it takes 14 to 17 months to register a generic product. This trend is expected to continue.

The new drug laws allow companies to make generic versions of off patent brand name drugs if they can prove to the FDA that their versions are equivalent to the brand name products. The requirement to repeat the studies to prove the safety and efficacy of established pharmaceutical compounds is no longer required. These new rules have created a new wave of the future for the pharmaceutical industry; Ciba Geigy, Smith Cline, American Cyanimid's Lederle Laboratories, Glaxo and Hoechst have all jumped into the generics marketplace because this is the place for future growth. (Ciba Geigy, American Cyanimid and Hoechst are also pesticide manufacturers and members of NACA). Additionally, several major U.S. drug patent holders have applied for patent term extension. It appears that the law is working as intended by Congress.

Will the major agricultural chemical companies who are producing these new products stop research and development if they do not receive extension of their patents? Will these same companies stop researching and developing new products if generic pesticide registration passes? Will they slash their R&D budgets by $100 million per year over the next several years? We think not!

The tax laws provide major incentives for research and development through favorable deductions and tax credits. A large amount of the cost of research and development is the cost of personnel. Salaries, bonuses and the expenses for R&D personnel may be written off under the tax laws in the year in which costs are incurred. Similarly, materials used in R&D may be written off in that year. These write-offs are for all R&D costs, not just for costs of commercialized products. The costs of facilities where R&D is performed are capitalized and written off against taxes over several years. In addition to these benefits, investment tax credits are provided under the tax laws for any R&D that exceeds the R&D in a base period. These tax credits are extended in the present proposed tax bills.

Who is really paying for R&D? The American taxpayer. Does it not stand to reason that the major chemical companies will continue R&D when they pay next to nothing for R&D and stand to gain millions of dollars from any innovation that results from the taxpayer-paid R&D? Will Congress give the taxpayer patent term extensions? Or, better yet, let's take two or three years off the patent to pay back our taxpayers for their R&D.

We agree that the generation of data costs a great deal of money, but who actually pays for the data? Using generally accepted accounting practices, the cost of R&D is usually written off in the year the costs were incurred, up to 50 percent. There is also an R&D tax credit which provides another 25 percent write-off up front. This could mean that 75 percent of the cost of data is paid for by the American taxpayer.

A central argument raised in favor of patent term extension is that innovation is declining under existing law. The amount being spent on research and development is not declining. The U.S. chemical industry (including, but not limited to, pesticides and other farm chemicals) boasted profits of $4.25 billion in 1986, an 8 percent increase over the previous year. Other companies in the Business Week (June 22, 1987, pp. 144-145) survey reported profits as high as 15 percent above 1985 profit levels.

Another gauge of the state of the chemical industry is R&D expenditures for the year. The average annual R&D expenditure was 6 percent higher in 1986 than it was in 1985, with some companies posting R&D expenditures as high 11 and 14 percent above the previous year, according to Business Week. The chemical industry appears to have no need to worry about a potential decrease in R&D following the implementation of generic registration, given these figures.

Also, chemical companies are pouring a considerable percentage of their profits back into R&D. In fact, the industry reported that an average of 48.6 percent of its pretax earnings went directly into its R&D facilities during 1986. That's right, nearly one-half of the nation's chemical industry's profits went directly into research for creating new chemicals, chemicals that will benefit U.S. consumers and U.S. farmers. Some members of the chemical industry reported even higher figures. One company in the Business Week survey reported that 95.9 percent of its pretax earnings were recycled to its R&D facilities. Do these figures reflect an industry where R&D is "drying up?" We think not.

CHEMICAL INDUSTRY
PROFITS AND RESEARCH AND DEVELOPMENT

Company	Profits		R&D		
	1986 (millions of dollars)	Percent annual change (1982-86)	1986 (millions of dollars)	% change from 1985	% of pretax profits
American Cyanamid	202.5	7	278.3	11	95.9
Dow Chemical	741.0	5	605.0	11	48.9
Du Pont	1538.0	11	1156.0	1	38.7
Ethyl	177.7	15	47.1	1	16.2
Great Lakes Chemical	26.8	12	13.2	9	30.9
Monsanto	433.0	7	523.0	11	82.2
Pennwalt	51.9	3	45.0	14	54.4
Rohm & Haas	138.0	10	132.8	8	60.6
Industry Composite	**4247.5**	**8**	**3662.2**	**6**	**48.6**

(Source: Business Week, June 22, 1987, PP. 144-145). See Appendix IX.

The National Agricultural Chemical Association (NACA) surveys for 1984 and 1985 reveal significant increases in R&D by as much as 39.3 percent in 1984 and 18.9 percent in 1985. We see no reason why the American agricultural chemical industry would cut back its R&D expenditures. In general, the R&D costs are usually recovered within a few years, if only because firms will not invest in products with low rates of returns.

	Total R&D expenditures	Increase from previous year	Percentage increase

	(in billions)		
1985	$868.9	$138.3	18.9
1984	$730.6	$206.2	39.3
1983	$524.4		

(See Appendix VII and Appendix VIII).

The 1985 industry survey shows that sales in the pesticide industry (including U.S. and non-U.S. production) were $5.37 billion in 1985. Research and development, on the other hand, resulted in 25 new compounds submitted for registration in 1985, 15 in 1984 and 11 in 1983--a steady increase of new products.

Basically, the manufacturer can recover significant portions of the cost of research and development through the operation of the tax laws. In addition, the regulatory statute governing the sale and distribution of pesticides, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) provides significant protection to the basic manufacturer after a patent has expired. A person can distribute a pesticide if he obtains a registration from EPA. To obtain a registration, the applicant must submit test data that demonstrates that the pesticide will not cause unreasonable adverse effects to individuals or the environment. This requirement for submission of test data applies to all patents, unlike human drugs and the proposed amendments to animal drug laws, even if the pesticide is a generic pesticide identical in all respects to a pesticide that had previously been approved by EPA.

We fully realize the importance of research and development for the pesticide industry and the need to generate new chemicals for future needs. Farmers, consumers and pesticide users depend on the development of new products to increase crop yield, protect against serious infestations and improve the quality of life for all Americans.

The current law and the 1987 proposed amendments go to great lengths to protect the investment interests of the original manufacturer, but we have done nothing to advance the interests of the farmers, ranchers, users and consumers who would benefit from greater generic competition and lower prices.

We support legislation H.R. 2569/S. 746 that is not intended to deprive basic manufacturers from recouping their R&D costs for both successful and unsuccessful products, as well as receiving an ample return on their investment.

If we combine a 17-year patent life with a five-year extension of the patent (H.R. 1345), 22 years in all, there ought to be sufficient incentive for innovation and adequate time to recoup all of the R&D costs.

It is time to resolve this long standing inequity.

The generic producers believe that there is a concerted effort by the brand name manufacturers to keep out competition. In the recent hearings on FIFRA, the generic producers of pesticides sought the inclusion of a reasonable standard for determining data compensation to be included in the law. The major brand name companies have consistently testified against fairness in pesticide laws and a definition of reasonable compensation. Each day that the brand name companies can prevent generic manufacturers from entering the market adds significant dollars to their bottom line at the expense of the American farmer and the American consumer. Again, the bottom line is not innovation or the need for more research and development, but corporate greed.

The same principle that gave rise to reversing the Bolar/Roche decision for the human drug industry holds true for pesticides. The need of the American farmer cannot be denied. To be competitive, we must give our farmers the best and least expensive tools with which to produce their crops.

We realize that many members of this Subcommittee are committed to giving patent term restoration for the major pesticide producers because of their sincere belief that the extension is fair in order to make up for lost patent time. We would appreciate your looking at the entire picture with a view toward fairness if you are thus committed. A fairness that would treat the pesticide patent term restoration bill the same as you treated drugs and are now treating animal health products. We believe that you owe this to the American farmer, the generic producers and the public at large.

A Compromise Solution to FIFRA:

During each of the last three congresses, the business issues of FIFRA, not the controversial environmental concerns, have generated sufficient conflict and dispute so as to frustrate the passage of the needed pesticide amendments.

We would like to see these disputes over the business issues within FIFRA resolved to the satisfaction of the basic manufacturers, the generic pesticide producers and the consumers and farmers who utilize agricultural pesticides.

We at CPDA want to commend Congressman Charles Hatcher (D-Ga.) for introducing H.R. 2569, the Pesticide Price Competition Act. This legislation would expedite the manufacturing of generic pesticides.

We believe that the Hatcher bill offers the best hope to resolve one of the most difficult and controversial issues of FIFRA--generic pesticide registration and data compensation. In a recent statement in the Congressional Record, Congressman Hatcher pointed out:

> "Now is the time to offer a compromise--a compromise that would generate generic pesticide registration and would increase competition while lowering prices for farmers, ranchers, users and consumers. If combined with legislation, H.R. 1345 and H.R. 2463, introduced by Congressmen George Brown, Kika de la Garza, Edward Madigan, Pat Roberts and others, it would be possible to aid basic pesticide manufacturers, generic producers and consumers. In a spirit of compromise, I offer this legislation as a means of resolving one of the most complex and controversial aspects of FIFRA legislation. If Congress fails to act on this matter, we will be doing a great economic injustice to the American farmer.
>
> By adopting this legislation as part of a larger FIFRA amendment package, the Congress could inject a healthy dose of competition into the pesticide industry and give farmers and consumers a real break. And we can help farmers and consumers without costing the Treasury or the American people a single penny."

We share his concerns. We commend his courage.

We applaud his spirit of compromise and respectfully urge the subcommittee and full committee to couple the Hatcher bill with future patent term restoration amendments, thus achieving a united approach that provides significant benefits to the basic manufacturers, small generic manufacturers, and farmers and consumers.

It is time to give the farmer a break. It is time to lower the farmer's cost of production without taking a penny out of the federal treasury. It is time to lower pesticide prices to consumers. It is time to give the pesticide industry a shot of deregulation. And it is time to work out a reasonable and workable compromise on the business issues of FIFRA.

We welcome any questions that the subcommittee might have.

APPENDIX I

PESTICIDES AND THE COST OF PRODUCTION: POTENTIAL FARM SAVINGS OF H.R. 2569/S. 746

Crop*	1985 cost of chemicals per acre***	1985 chemical percentage of cash variable expenses	Savings per acre if prices drop 20 % due to generic competition
Corn	$17.58	8.6%	$3.52
Sorghum	8.52	13.4%	1.70
Barley	5.43	10.4%	1.09
Oats	1.11	.3%	.22
Wheat-all	2.93	5.9%	.59
Spring wheat	5.09	12.5%	1.02
Durum wheat	5.35	14.2%	1.07
White wheat	9.58	12.9%	1.92
Winter wheat	1.50	3.3%	.30
Rice	26.88	10.8%	5.38
Soybeans	17.47	32.3%	3.50
Sunflower	13.30	27.3%	2.66
Peanuts-all	79.63	29.3%	15.93
" southeast	94.58	33.0%	18.92
" VA & NC	88.76	28.7%	17.75
Flax	4.15	13.6%	.83
Cotton-all	45.18	20.5%	9.04
" Delta	72.27	32.3%	14.45
" southeast	96.04	35.7%	19.21
Sugar beets	44.57	15.3%	8.91
" TX and NM	101.13	22.9%	20.21
Sugar cane	56.44	7.5%	11.29
" Hawaii	125.64	4.8%	25.13
Tobacco**			
" burley	70.08	3.6%	14.02
" flue-cured	94.44	4.6%	18.89

* Economic Indicators of the Farm Sector, Costs of Production, 1985 (United States Department of Agriculture, Economic Research Service, ECIFS 5-1.

** Annette Clausen, Economic Research Service, USDA.

*** Chemical category does not include fertilizers.

America in *Congress assembled*, That (a) section 1814(a)(2)(D) of the Social Security Act is amended by inserting ", occupational," immediately after "physical".

(b) Section 1835(a)(2)(A)(i) of such Act is amended by inserting ", occupational," immediately after "physical".

(c) Section 1835(a)(2) of such Act is further amended—

(1) by striking out "and" at the end of subparagraphs (B) and (C);

(2) by striking out the period at the end of subparagraph (D) and inserting in lieu thereof "; and"; and

(3) by adding after subparagraph (D) the following new subparagraph:

"(E) in the case of outpatient occupational therapy services, (i) such services are or were required because the individual needed occupational therapy services, (ii) a plan for furnishing such services has been established and is periodically reviewed by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician.".

(d) The last sentence of section 1864(p) of such Act is amended by inserting "and occupational therapy services" after "speech pathology services".

SEC. 2. The amendments made by the first section of this Act shall be applicable in the case of services furnished on and after the first day of the first month which begins not less than thirty days after the date of the enactment of this Act.

FIFRA, "EXCLUSIVE USE," AND JUSTICE DEPARTMENT OPINION

HON. FLOYD J. FITHIAN

OF INDIANA

IN THE HOUSE OF REPRESENTATIVES

Monday, October 31, 1977

Mr. FITHIAN. Mr. Speaker, today, we are considering amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). One of the most important aspects of this legislation is the implementation of a 5-year period of "exclusive use of data," in which the company or pesticide registrant would have sole proprietary use of that data. Although I would have preferred a mandatory licensing system with compensation spread over nearly 10 years, I supported this effort in the spirit of compromise so that the legislative process could be expedited.

In my view, this provision of the FIFRA amendments is very generous to the manufacturers of technical grade pesticides—generous perhaps to a flaw. It should be a continuing responsibility of the House Agriculture Committee to assure that our action today does not exacerbate the growing tendency toward oligopoly in the pesticide manufacturing industry.

The Department of Justice, in two letters to me, clearly have stated their objections to the "exclusive use of data," pointing out that it would be harmful to competition in the pesticide industry. If the FIFRA amendment proposed today do not reverse this trend, the Congress will have an obligation to return to this legislation with further corrective action. And this action might be necessary.

For the benefit of my colleagues in the House, I am inserting the two letters from the Department of Justice in the RECORD.

WASHINGTON, D.C.,
September 6, 1977.

Hon. FLOYD J. FITHIAN,
House of Representatives,
Washington, D.C.

DEAR CONGRESSMAN FITHIAN: This is in response to the request of your staff for the views of the Department of Justice on the so-called "industry compromise" presented by the National Agricultural Chemicals Association ("NACA") regarding the trade secret and data compensation provisions in the Federal Insecticide, Fungicide and Rodenticide Act.

As we have previously indicated in response to other inquiries, we find the NACA proposal to be unacceptable. The NACA proposal basically relies upon an "exclusive use of data" concept. While it may be true that use of data and patent rights are technically distinguishable, as NACA argues, we think it equally true that both entail potential monopoly and monopoly profits, and we adhere to our expressed views that exclusive use of data may be, for all practical purposes, an extension of a patent monopoly. Thus, we continue to oppose exclusive use of data, in the belief that its impact on the industry (and on consumers) would likely be comparable to the impact of the Act as discussed in the recent EPA report.

We would not attempt to predict the likely impact of NACA's limited data sharing proposal, to take effect in the event of additional data requirements, and in particular of the fall-back "equal" cost sharing concept. In any event, this concept appears to exclude new registrants.

In summary, we adhere to the views we have previously expressed. We also believe that Congress should keep in mind that a "compromise" among some segment of affected industries is not necessarily in the interest of the public.

Sincerely,

PATRICIA M. WALD
Assistant Attorney General.

WASHINGTON, D.C.,
April 27, 1977.

Hon. FLOYD J. FITHIAN,
House of Representatives,
Washington, D.C.

DEAR CONGRESSMAN FITHIAN: This is in response to your letter of April 22, 1977, concerning the competitive effects of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), a key area of concern to you and your colleagues as you consider proposed amendments to the Act. You ask for our evaluation of the "climate for competition" under present law, and enclose a copy of the recent EPA Report, "FIFRA, Impact on the Industry." You also ask for any comments we may have on conflicting proposals to resolve competitive issues.

The Antitrust Division prepared comments for the Agriculture Committee concerning aspects of FIFRA in a letter responding to an inquiry by Representative James P. Johnson. These comments were made part of the record of the oversight hearings on March 7. A copy of that letter is attached.

The Department of Justice supports the EPA's evaluation and conclusions with respect to the direct and indirect anticompetitive effects of the trade secret provisions of Section 10 of FIFRA. We concur with EPA that some expression of Congressional intent would be desirable to support the Agency's position on the issues relating to competition in the pesticide industry.

However, we feel that the EPA report has not fully explored all of the competitive issues, and we are opposed to certain recommendations made to EPA, as outlined in the Appendix to its Report.

1. Data Disclosure and Trade Secret Exemption. The EPA report examines the impact of the data licensing, public access, and trade secret provisions (§§3(c)(1)(D), 3(c)(2) and 10) of FIFRA[1] upon competition in the pesticide industry. The conflict between sections 3(c)(1)(D) and 10 has generated much of the controversy surrounding FIFRA. Ten suits have been filed in various federal courts to prevent the EPA from disclosing data which the data producing firms (i.e., developers)[2] claim are trade secrets and thus nondisclosable under § 10. Representative Johnson's request for the Antitrust Division's comments on FIFRA was prompted by a complaint that one major data producing firm was using the § 10 trade secret exemption to extend its patent monopoly past the expiration of its patents.

The Antitrust Division's letter to Mr. Johnson delineates its views concerning sections 3(c)(1)(D) and 10. The Division's letter concludes that the scope of the trade secret provisions of FIFRA may have been improperly extended in denying potential competitors access to test data prepared by developers. We agree with the position of EPA that "trade secret status should be routinely extended only to truly secret information concerning manufacturing processes (and, perhaps, to the list of deliberately-added inert ingredients in formulated, end-use products."[3]

2. *Extension of Patent Protection.* The data producing firms have argued that the generation and compilation of data necessary to register a new pesticide appreciably diminishes the duration of patent protection from the statutory 17-year period to about 12 years. This justifies, it is suggested, the broad interpretation of section 10: an effective extension of the patent period is necessary to make up for the time lost developing the data, and claiming trade secret status for all data provides that extension. A separate but related argument is that availability of the data (whether by opening the files, or by disclosure, or by allowing referencing of the data without actual disclosure) is a disincentive to development of new pesticides; therefore, disclosure is at the expense of research and development directed toward new and innovative pesticides. These considerations may be the basis for a recommendation to EPA (see Appendix of EPA Report, at 79) to lengthen patent protection, as one of several possible actions that would allegedly foster pest control research and development.

We find both industry arguments unconvincing. The former ignores the fact that patents of this nature are typically pending for several years before the patent is granted (when the period of protection begins to run), thus giving the patent owner considerable time to conduct testing necessary for registration. The latter is contrary to actual experience. The pesticide industry existed from 1947 through 1972 without any legislation protecting the confidentiality of registration data—a period during which the USDA and its successor, the EPA, freely and openly referred to all data in connection with applications for registration of pesticidal formulations similar to those previously registered. If there was a disincentive

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See pages 6, 9, 10, 11, 20-22 of the EPA Report.

It should be noted that the EPA raises two separate issues: (1) the access to or reliance upon safety, efficacy, environmental chemistry data ("test data"), without actual disclosure, which has been furnished to EPA by developers, and (2) the public disclosure of such data. The Department believes that the competitive issues hinge principally on the ability of applicants to use such test data to satisfy registration requirements.

[1] For description of these provisions, see attachment, pp. 2-5.

[2] This term is used to identify firms that have produced data to support registration. These firms are generally large, R&D-oriented companies.

[3] See page 11 of EPA Report.

toward research and development, it did not manifest itself in any decline in new pesticide registrations. It is curious that the asserted need for protection of test data became evident only when significant numbers of pesticide patents began to run out. We find the disincentive argument somewhat disingenious.

We also find the extension of patent protection inconsistent with long-standing law accommodating the patent laws with our system of free competition. The courts have held that the patent grant, as an exception to the competitive system's general prohibition of monopolies, must be strictly confined to its boundaries. Attempts to extend the scope or duration of patent monopoly have been routinely struck down. See, e.g., *Brulotte v. Thys Co.*, 379 U.S. 29 (1964) (post-expiration royalties not permitted); *Hartford Empire Co. v. United States*, 323 U.S. 386 (1945) (pooling of patents to effect monopoly control of entire industry illegal). Any proposal having the effect of extending the patent protection beyond the statutory period would be inconsistent with existing law and with the spirit of free competition. Furthermore, since the inception of our patent laws, Congress has provided a single period of patent protection for all industries. We see no reason for a special exception for the pesticide industry.

3. Compensation. Section 3(c)(1)(D) requires that applicants compensate, or offer to compensate, owners of test data for use of data in processing their applications for registration. The use of compensation is not discussed at length in the EPA Report, perhaps because problems in determining what data is available for referencing have been so formidable that the issue of availability and compensation has not arisen frequently.

There are several considerations which bear on the issue of compensation for the use of test data. Patent owning, data producing firms may be amply compensated during the 15 to 17 year period in which they can exact monopoly prices from consumers. Prior to the 1972 FIFRA amendments, when generic producers could economically manufacture technical pesticides upon expiration of the patent, prices typically dropped dramatically upon patent expiration. For example, the price per pound of DDT fell to about ¼ of the pre-expiration price when competition was introduced, suggesting that monopoly profits were quite significant (and likely adequate to cover registration costs).

We think it should also be kept in mind that the compensation provisions could be used to effect anticompetitive ends in dealing with both competing manufacturers of technical pesticides and formulators of end-use products from the technical materials. There are inherent problems in determining what constitutes "reasonable" compensation for data. Thus, the provision could provide a tool for extending patent monopoly by pricing data out of reach of small competing manufacturers and for exercising control of the end-use and/or end-users after initial sale of the patented material.[6] We consider both types of action inconsistent with competitive policy.[7]

Finally, there is a serious question as to the appropriateness of requiring formulators to compensate developers for the use of test data, a cost which could be reflected in the price of technical-grade chemicals purchased from the developers. We agree with EPA that primary data compensation should be limited to "registrants of technical, rather than end-use products."[8]

4. Vertical Effects. The area of horizontal competition between manufacturers is the primary focus of the EPA report. However, FIFRA also provides a mechanism for control of certain vertical aspects of distribution of formulations of the technical material. FIFRA currently requires that each formulation of a pesticide be registered by each firm that distributes the formulation. Thus, if Firm A, the patent owner and producer of data for pesticide X, sells the technical form of X to Firm B, which desires to make a 50 percent concentration of X for use on soybeans, Firm B must obtain a registration for its 50 perecnt formulation. The majority of the data that Firm B would be required to provide relates to the technical form of X and would have been submitted to the EPA by Firm A when it registered X. If Firm B has Firm A's permission, it can reference this data and will need to provide only relatively inexpensive efficacy data relating to the particular concentration, target pests and protected crops. If, as is frequently the case, Firm A also markets a 50 percent formulation for use on soybeans, Firm B may incur no major expense at all in registering its formulation.

However, control over data by Firm A may allow it to control use of pesticide X by Firm B (perhaps exercised by insisting that Firm B market X only in certain formulations in which Firm A has no interest). Firm A may also use its control of data to attempt to limit resale of pesticide X to other firms. Thus, limits on availability of data can have serious anticompetitive effects in a vertical sense.

Rejection of the broad definition of trade secrets urged by the data producing firms would make most data available without the need for permission from the data producing firm. Elimination of the compensation requirement would further diminish the risk of vertical restraints, but a reasonable compensation provision that eliminates uncertainty as to price and is inapplicable to formulators would be inconsistent with antitrust principles.

5. Product Leverage. In its discussion of advantages which the patent owner enjoys over potential manufacturers upon expiration of a patent, the EPA report neglects one substantial advantage. The patent owner is, as the report suggests, likely to be a large chemical firm that may sell, in addition to its once-patented pesticide, a variety of pesticidal products (or other chemical products) through a distribution channel of independent formulators. A distributor might be dissuaded from purchasing the once-patented pesticide from a new, cheaper supplier by the risk of losing the broader product line offered by the original manufacturer. If this "product line leverage" rises to threats or requirements that the distributor continue to purchase the now unpatented pesticide or lose the full product line the antitrust laws may have been violated.

6. Impact of Reregistration. The reregistration process has a potentially destructive effect upon existing competition in the manufacture of technical pesticides. Prior to enactment of the 1972 amendments, several generic manufacturers obtained registrations on technical grade pesticides where patents had expired and began to manufacture a market those pesticides. Registrations we obtained without submitting any suppor data. When these pesticides are called in for reregistration however, each registration will have to be supported by adequate t[illegible]ata. Because practically all such data [illegible]ubmitted prior to 1970, compensation [illegible]not a barrier to continued competition, but availability of the data (through reference or disclosure) is a problem. (The data producing firms' position on trade secrets, if adopted by Congress, could eliminate what little competition does exist in the manufacture of technical grade pesticides.)

7. Data on Impurity Standards. The debate on impurity standards may be a forerunner of other similar problems in data referencing. We understand that at least one of the major data producing firms is prepared to assert that EPA may not use the firm's technical pesticide formula for comparison when registering a "me too" firm's version of the pesticide upon expiration of the patent. Thus even if the "me too" manufacturer could properly reference all the required data, the original manufacture could prevent registration by prohibiting EPA from comparing the two technical formulae to determine whether the "me too" manufacturer's product contains more or different impurities.

8. Conclusion. The EPA report very adequately addresses the major competitive impasse in FIFRA—the interplay between sections 3(c)(1)(D) and 10. The Department of Justice would strongly oppose any attempt to resolve the problems by expanding patent protection through either lengthening the duration of patent protection or adoption of the broad definition of trade secrets urged by the data producing firms.

We understand that many of the problems discussed above are addressed in amendments to FIFRA being proposed by EPA. We hope our views will be of assistance to the Subcommittee in its consideratio[illegible] the competitive issues presented by FIF[illegible]

Sincerely yours,

DONALD I. BAKER,
Assistant Attorney General,
Antitrust Division.

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[6] See ¶ 4, *infra*.

[7] On February 23, 1977, the Department of Justice filed a proposed consent decree that would settle an antitrust action brought against Union Carbide charging restraint on resale and use of its technical pesticide carbaryl. The consent decree requires Union Carbide to assist formulators in obtaining registrations by making data available for EPA use. Union Carbide is also prohibited from collecting compensation for any data that has been used free of charge by another applicant. This free licensing provides an important precedent.

We also note that Union Carbide typically did not charge any fee for its vendees' use of its data on file with the EPA. Apparently Carbide saw no disincentive in the access to its data.

[8] See EPA Report at 20.

SANCTIONS FOR SOUTH AFRICA

HON. ROBERT L. F. SIKES

OF FLORIDA

IN THE HOUSE OF REPRESENTATIVES

Monday, October 31, 1977

Mr. SIKES. Mr. Speaker, the Washington Star, which is moderate in its political philosophy, has questioned the wisdom of sanctions for South Africa.

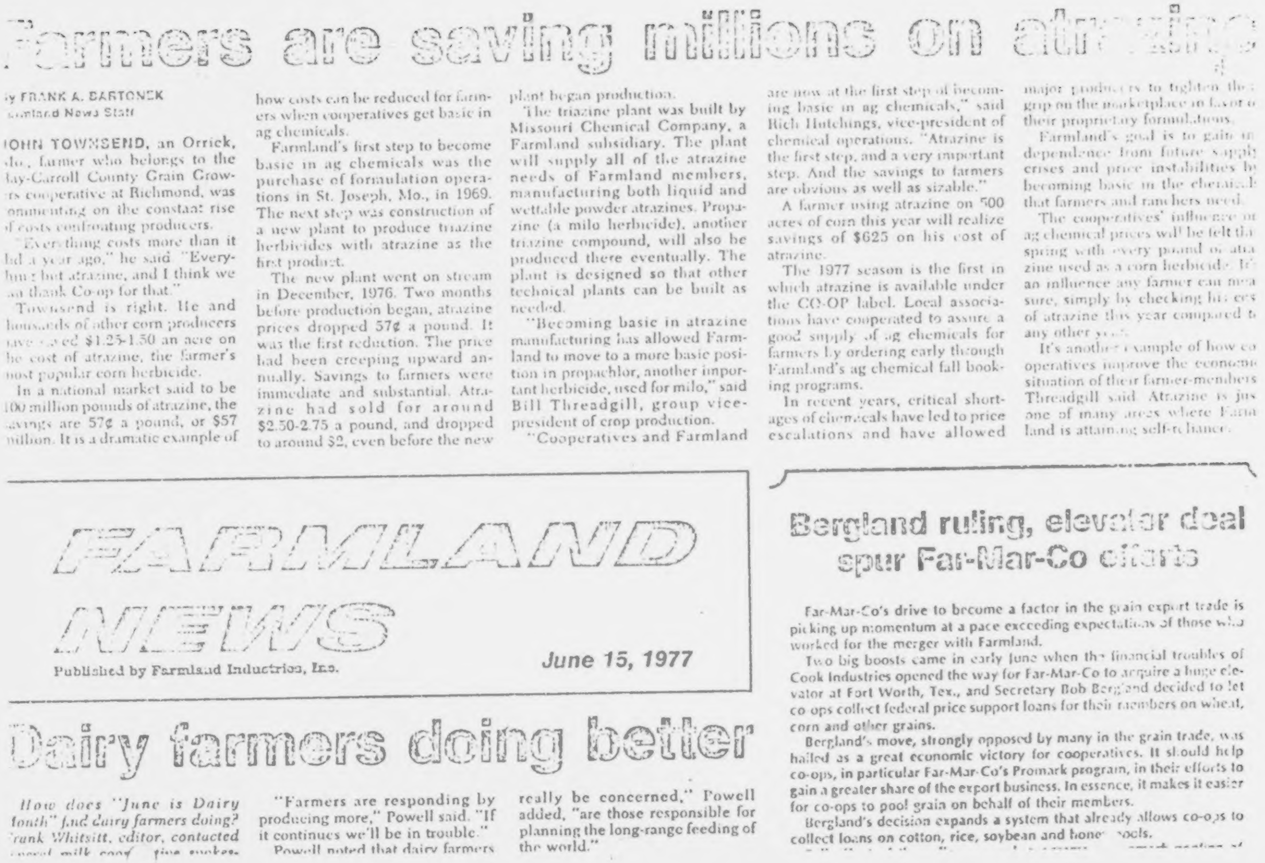
On Thursday, October 27, the Star published, in its editorial column, a studied approach to the problems which would arise from sanctions. The editorial provides an unusually keen insight into the generally indecisive policies of the United States on African questions.

I submit this article for reprint in the RECORD:

SANCTIONS FOR SOUTH AFRICA?

When he was asked recently to say why the United States presses South Africa harder on human rights issues than it does other alleged offenders, Iran and Brazil for instance, Mr. Zbigniew Brzezinski admitted that it was a tough question.

South Africa is a priority target for our moral hazing, Mr. Brzezinski sugges[illegible], because the "black-white" confrontati[illegible]here could so easily become as ideologic[illegible] racial: not only black-white but also "red-white," as he chose to put it.



Farmers are saving millions on atrazine

y FRANK A. BARTONEK
armland News Staff

OHN TOWNSEND, an Orrick, lo., farmer who belongs to the ay-Carroll County Grain Growrs cooperative at Richmond, was ommenting on the constant rise f costs confronting producers.

"Everything costs more than it ad a year ago," he said. "Everyhing but atrazine, and I think we an thank Co-op for that."

Townsend is right. He and housands of other corn producers ave saved $1.25-1.50 an acre on he cost of atrazine, the farmer's most popular corn herbicide.

In a national market said to be 100 million pounds of atrazine, the avings are 57¢ a pound, or $57 nillion. It is a dramatic example of how costs can be reduced for farmers when cooperatives get basic in ag chemicals.

Farmland's first step to become basic in ag chemicals was the purchase of formulation operations in St. Joseph, Mo., in 1969. The next step was construction of a new plant to produce triazine herbicides with atrazine as the first product.

The new plant went on stream in December, 1976. Two months before production began, atrazine prices dropped 57¢ a pound. It was the first reduction. The price had been creeping upward annually. Savings to farmers were immediate and substantial. Atrazine had sold for around $2.50-2.75 a pound, and dropped to around $2, even before the new plant began production.

The triazine plant was built by Missouri Chemical Company, a Farmland subsidiary. The plant will supply all of the atrazine needs of Farmland members, manufacturing both liquid and wettable powder atrazines. Propazine (a milo herbicide), another triazine compound, will also be produced there eventually. The plant is designed so that other technical plants can be built as needed.

"Becoming basic in atrazine manufacturing has allowed Farmland to move to a more basic position in propachlor, another important herbicide, used for milo," said Bill Threadgill, group vice-president of crop production.

"Cooperatives and Farmland are now at the first step of becoming basic in ag chemicals," said Rich Hutchings, vice-president of chemical operations. "Atrazine is the first step, and a very important step. And the savings to farmers are obvious as well as sizable."

A farmer using atrazine on 500 acres of corn this year will realize savings of $625 on his cost of atrazine.

The 1977 season is the first in which atrazine is available under the CO-OP label. Local associations have cooperated to assure a good supply of ag chemicals for farmers by ordering early through Farmland's ag chemical fall booking programs.

In recent years, critical shortages of chemicals have led to price escalations and have allowed major producers to tighten their grip on the marketplace in favor o their proprietary formulations.

Farmland's goal is to gain independence from future supply crises and price instabilities by becoming basic in the chemicals that farmers and ranchers need.

The cooperatives' influence on ag chemical prices will be felt this spring with every pound of atrazine used as a corn herbicide. It's an influence any farmer can measure, simply by checking his cost of atrazine this year compared to any other year.

It's another example of how cooperatives improve the economic situation of their farmer-members, Threadgill said. Atrazine is just one of many areas where Farmland is attaining self-reliance.

FARMLAND NEWS

Published by Farmland Industries, Inc.

June 15, 1977

Dairy farmers doing better

How does "June is Dairy Month" find dairy farmers doing? Frank Whitsitt, editor, contacted

"Farmers are responding by producing more," Powell said. "If it continues we'll be in trouble."

Powell noted that dairy farmers

really be concerned," Powell added, "are those responsible for planning the long-range feeding of the world."

Bergland ruling, elevator deal spur Far-Mar-Co efforts

Far-Mar-Co's drive to become a factor in the grain export trade is picking up momentum at a pace exceeding expectations of those who worked for the merger with Farmland.

Two big boosts came in early June when the financial troubles of Cook Industries opened the way for Far-Mar-Co to acquire a huge elevator at Fort Worth, Tex., and Secretary Bob Bergland decided to let co-ops collect federal price support loans for their members on wheat, corn and other grains.

Bergland's move, strongly opposed by many in the grain trade, was hailed as a great economic victory for cooperatives. It should help co-ops, in particular Far-Mar-Co's Promark program, in their efforts to gain a greater share of the export business. In essence, it makes it easier for co-ops to pool grain on behalf of their members.

Bergland's decision expands a system that already allows co-ops to collect loans on cotton, rice, soybean and honey pools.

Appendix IV

PATENT TERM EXTENSION AMENDMENT

Same as 1986 House and Senate passed bills (i.e., up to a 5 year patent extension to compensate for regulatory delays, 3 years if the review period began before enactment of the bill, none if regulatory review completed by enactment) except that there is no termination date for the amendment and except for inclusion of a provision to reverse the holding of the court in Roche Products v. Bolar Pharmaceutical Co. Inc. as follows:

Section 271(e) of title 35, United States Code, is amended by--

(1) redesignating paragraphs (3) and (4) as paragraphs (4) and (5), respectively;

(2) adding a new paragraph (3) as follows:

"(3)(A) During the term of a patent relating to a pesticide (including a patent which claims a pesticide, a method for using a pesticide, or a method of manufacturing a pesticide) which is or has been registered under the Federal Insecticide, Fungicide, and Rodenticide Act or which is marketed with the permission of the holder of such patent, it shall not be an act of infringement of such patent to make, use, or sell such pesticide solely for testing reasonably related to the development and submission of data-

"(i) to meet regulatory requirements under the Federal Insecticide, Fungicide, and Rodenticide Act,

"(ii) to obtain a tolerance or an exemption from a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act, or

"(iii) to obtain a food additive regulation or an exemption from a food additive regulation under section 409 of the Federal Food, Drug, and Cosmetic Act.

(B) It shall be an act of infringement for any person to submit any application under the Federal Insecticide, Fungicide, and Rodenticide Act or section 408 or 409 of the Federal Food, Drug, and Cosmetic Act for a pesticide covered by a composition of matter patent, method of use patent, or method of manufacturing patent issued for the pesticide if the purpose of the submission of such application is to obtain approval of such application to engage in the commercial manufacturing, use, or sale of a pesticide covered by such patent before the expiration of such patent, unless such person is the holder of such patent or a licensee of the holder.

(C) For purposes of this paragraph, all formulations of a pesticide containing the identical active ingredient shall be considered the same pesticide.";

(3) amending paragraph (4), as redesignated, by inserting "or paragraph (3)(A)" after "paragraph (1)"; and

(4) amending paragraph (5), as redesignated, by--

(A) inserting "and paragraph (3)(B)" after "paragraph (2)", wherever it appears in such paragraph; and

(B) inserting "or pesticide" after "drug" wherever it appears in such paragraph.

The Committee for Research and Development of Agricultural Chemicals
1627 K Street NW
Suite 500
Washington, D.C. 20006
202 956 5200

FIFRA FACT SHEET

Agrichemical Industry at a Glance

Total domestic U.S. sales for pesticides were $4.06 billion in 1985, down 9 percent from $4.46 billion in 1984. Total U.S. herbicide sales in 1985 were $2.6 billion and insecticide sales were $968 million. Total U.S. fungicide sales were $269 million in 1985. (Source: 1985 Industry Summary for reporting companies from the National Agricultural Chemicals Association (NACA).)

The industry employs about 95,000 in manufacturing, research and development, distribution and sales in the U.S. The products are used in all 50 states by several million farmers, ranchers and applicators.

Major applications of pesticides are for such crops as corn, wheat, soybeans, rice and cotton. Smaller applications by volume, but no less important to the farmers that use them, are for fruit and vegetable crops such as peaches, apples, carrots, cherries, avocados, tomatoes, peanuts and pecans.

From Research to Market

In 1985, of the 26 innovative companies reporting, a total of 185,013 compounds were researched and brought to a screening process. This process determines which compounds are likely to show some scientific or market potential. Then the compounds are submitted to long-term "feeding" or application tests.

The elapsed time from first discovery, through long-term feeding studies, to submission for first commercial registration for a product takes an average of 89 months or just over seven years. In 1985, this process resulted in a total of three new compounds receiving their first full registrations.

From the submission of the registration package until the granting of registration to market means an additional two years before a product can be marketed.

1985 research and development (R&D) expenditures for new products were $553 million or 67 percent of the total R&D costs for the industry.

(please turn)

APPENDIX VI

U.S. Pharmaceutical Industry Sales & R&D Expenditures, 1961-1986[a] (millions of dollars) 1

Year	U.S. Sales[b]	Global Sales and R&D-PMA Member Firms		
		Sales Human and Veterinary[c]		R&D[d]
	Human Dosage	*Dosage Only*	*Dosage & Bulk*	*Human & Veterinary*
1986[e]	24,774	34,567	36,064	4,647
1985	22,065	30,698	32,026	4,078
1984	19,345	28,615	29,854	3,579
1983	17,278	26,254	27,506	3,218
1982	15,394	24,466	25,654	2,774
1981	13,000	22,378	23,530	2,340
1980	11,799	21,460	22,515	1,977[f]
1979	10,044	17,789	18,939	1,627
1978	9,156	15,463	16,431	1,404
1977	8,233	13,377	14,155	1,276
1976	7,669	12,295	13,035	1,164
1975	6,895	11,129	11,769	1,062
1974	6,083	9,755	10,361	942
1973	5,507	8,403	8,839	825
1972	5,018	7,576	7,930	726
1971	4,667	6,787	7,605	684
1970	4,322	6,226	6,637	619
1969	4,008	5,632	6,008	550
1968	3,655	5,097	5,482	495
1967	3,226	4,546	4,941	461
1966	3,011	4,105	4,509	416
1965	2,779	3,758	4,136	365
1964	2,479	3,331	3,643	310
1963	2,317	3,082	3,399	292
1962	2,199	2,866	3,170	259
1961	1,954	2,626	2,933	245

[a] Additional data are available to 1954. See earlier Annual Survey Reports.

[b] U.S. Sales of finished prescription and "other ethical" dosage forms.

[c] Global sales are defined to include total ethical pharmaceutical sales within the United States, exports to nonaffiliated firms and sales abroad of U.S. affiliates. Figures apply to PMA member companies only. Historical series has been adjusted accordingly.

[d] Global R&D includes all ethical pharmaceutical research and development financed or conducted by U.S. pharmaceutical companies in the U.S. and abroad, and in the U.S. only by U.S. based subsidiaries of foreign-owned firms.

[e] PMA estimates based on member company budgeted figures or estimates.

[f] R&D figures for 1979 and 1980 reflect a 21% increase in expenditures, however, part of this increase is due to improved reporting of expenditures in foreign countries. Adjusting for this improved reporting results in an 18% increase.

Appendix VII

1984
INDUSTRY PROFILE SURVEY

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

Ernst & Whinney
Washington, D.C.

Because of Competition Farmers have a Choice

On average, there are 3.7 companies holding registrations on each of the off-patent herbicides in the group of 20 top-selling chemicals. For most of the major crops (wheat, corn, etc.), there are at least 6 registered herbicides available for different weed control problems. Based on an average of 3.7 companies in each of the 6 major user markets, farmers have some 22 products from at least 8 different companies to choose from.

For example, soybean farmers in states like Georgia had more herbicides introduced in 1986 to control weeds than in any other year, according to the University of Georgia Extension Service. These new options, developed by innovative agrichemical producers, include: Scepter, an American Cyanamid chemical; Classic, Canopy and Gemini from Du Pont Company; Command from FMC Corp.; and Tackle, made by Rhone-Poulenc. Appropriate use of these new herbicides with established methods of application should improve weed control and lower per-acre costs for the farmers.

What's at Stake in the Data Compensation Issue

For any agrichemical registered after September 30, 1978, companies submitting safety and health data qualify for 10 years of exclusive use of their data, followed by five years during which compensation must be paid by a follow-on registrant. Compensation will become an issue for these chemicals starting in late 1988.

In the next few years, about two dozen major, well-established chemicals will go off-patent. These compounds were registered between 1970 and 1978 and are among the most effective and most profitable in use. By the late 1980s or early 1990s, virtually all the original data submitted in support of these pesticides will no longer be compensable.

Follow-on registrants will be able to use this information, which cost the initial registrants an average of $12 million for health and safety studies, without paying any research and development (R&D) costs at all.

By the end of 1990, about a dozen of the post-1978 active ingredients will become prospects for market entry and compensation.

(please turn)

Decline of Important R&D for Better Chemicals if FIFRA is Amended Now.

If Congress amends FIFRA to allow low-cost access to health and safety data for follow-on registrants, 20 to 40 percent of agrichemical sales, $2 to $3 billion annually, will shift to follow-on registrants. As a result, private sector R&D in agrichemicals will decline by $100 million or more each year -- from a base of $553 million in 1985 (according to the NACA survey).

The R&D that is being done by initial registrants is critical if newer and safer chemicals are to be brought to market. Without R&D, it will not be economical to develop less toxic, less persistent chemicals.

Follow-on registrants do not participate in innovative R&D efforts to bring new, more efficient compounds to market.

Small Farmers Hurt Most as Less R&D means "Orphan Crops"

Minor crop growers will be the first to suffer from a reduction in R&D for newer and better chemicals. Farmers who produce comparatively small market crops such as fruits and vegetables will be the first to lose the benefit of improved pesticide products as the return on R&D is reduced drastically. If FIFRA is changed to permit less return on R&D costs, the nation will face the problem of "orphan crops" -- those that get less and less of the R&D time, effort and money.

Maintaining U.S. Markets for U.S. Innovative Producers

Pesticides are one of the few U.S. industries with a favorable trade balance, having 1985 export sales of $1.32 billion, while imports of foreign products amounted to $713 million. The United States is the largest pesticide market in the world, and many giant foreign corporations (for example, Mitsubishi in Japan) want to take advantage of the U.S. pesticide registration system.

By relying on the data of an innovative agrichemical company that guided a compound through the EPA registration process and by forming a partnership with a follow-on registrant, a foreign manufacturer will be able to "raid" already established U.S. markets, having conducted no research and development to benefit U.S. farmers. And the access to the market will be accomplished at very little business risk to themselves.

rda102.lqp

SCHEDULE 5-A

RESEARCH AND DEVELOPMENT EXPENDITURES, SCREENING AND PRODUCT REGISTRATION

Composite Analysis of All Reporting Companies

	Number Reporting*	Year		Percent Change
		1983	1984	
I. Total R&D Expenditures	28	$524,428,000	$624,364,000	+ 19.1
II. Total Compounds Screened	28	133,297	143,752	+ 7.8
III. Number of New Tolerance Products Receiving First Full Registration:	6	5	3	
IV. Number of Compounds Submitted for First Full Registration:				
Tolerance Products	9	7	12	
Non-Tolerance Products	7	4	6	

	Average Elapsed Time Per Tolerance Product	
	Full Registration	
	1983**	1984
V. Elapsed Time Per Product		
A. Elapsed time from discovery to first long-term feeding study (months)	67	52
B. Elapsed time from starting first long-term feeding study to submission for first commercial registration (months)	39	35
C. Elapsed time from submission for first commercial registration to granting of first commercial registration (months)	18	31
D. Total elapsed time from discovery to first commercial registration (months)	98	118
E. Number of tolerance products revelving first full registration	5	3

* Number of companies reporting in 1983 and 1984.

** All companies were not able to report data for each category; the data shown are averages of information actually reported.

NOTE: Some companies were unable to report R&D expenditures due to some R&D being done overseas.

SCHEDULE 5--

RESEARCH AND DEVELOPMENT EXPENDITURES, SCREENING AND PRODUCT REGISTRATION

Composite Analysis of All Reporting Companies

	Number Reporting*	Year		Percent Change
		1984	1985	
I. Total R&D Expenditures	25	$730,576,000	$868,939,000	- 15.9
II. Total Compounds Screened	25	174,132	185,013	- 5.2
III. Number of New Tolerance Products Receiving First Full Registration:	5	3	3	
IV. Number of Compounds Submitted for First Full Registration:				
Tolerance Products	10	9	13	
Non-Tolerance Products	12	6	12	

	Average Elapsed Time Per Tolerance Product	
	Full Registration	
	1984**	1985
V. Elapsed Time Per Product		
A. Elapsed time from discovery to first long-term feeding study (months)	52	46
B. Elapsed time from starting first long-term feeding study to submission for first commercial registration (months)	35	43
C. Elapsed time from submission for first commercial registration to granting of first commercial registration (months)	31	25
D. Total elapsed time from discovery to first commercial registration (months)	118	114
E. Number of tolerance products receiving first full registration	3	5

* Number of companies reporting in 1984 and 1985.

** As reported in 1984 NACA Industry Profile Survey.

NOTE: R&D expenditures for 1984 and 1985 are not comparable due to some companies being unable to restate 1984 R&D expenditures on a world-wide basis.

APPENDIX IX

R&D SCOREBOARD

COMPANY	SALES			PROFITS		R&D EXPENSES				EMPLOYMENT	
	1986 MILLIONS OF DOLLARS	PERCENT CHANGE FROM 1985	PERCENT ANNUAL CHANGE (1982-86)	1986 MILLIONS OF DOLLARS	PERCENT ANNUAL CHANGE (1982-86)	1986 MILLIONS OF DOLLARS	PERCENT CHANGE FROM 1985	PERCENT OF SALES	PERCENT OF PRETAX PROFITS	R&D DOLLARS PER EMPLOYEE	ANNUAL CHANGE IN EMPLOYMENT (1982-86)
4 AUTOMOTIVE PARTS, EQUIPMENT											
INDUSTRY COMPOSITE	**14459.4**	**4**	**12**	**334.4**	**54**	**341.0**	**12**	**2.4**	**52.8**	**2119.2**	**6**
Champion Parts Rebuilders	110.0	9	4	0.6	−13	**1.3**	**−1**	**1.2**	**120.9**	**542.0**	1
Clark (J. L.) Mfg. (11)	150.6	−3	−1	17.4	8	**1.3**	**4**	**0.9**	**4.1**	**793.5**	−6
Clevite Industries	299.5	1	8	6.3	NA	**4.6**	**−4**	**1.5**	**50.3**	**1101.0**	NA
Cummins Engine	2303.7	7	11	−107.3	NA	**87.5**	**25**	**3.8**	**NEG**	**3804.3**	5
Dana	3695.1	−2	12	85.9	15	**51.0**	**11**	**1.4**	**26.6**	**1378.4**	6
Eagle-Picher Industries (11)	648.3	1	6	38.8	37	**17.1**	**35**	**2.6**	**24.7**	**2164.6**	3
Eaton	3811.6	4	13	137.6	11	**134.1**	**9**	**3.5**	**60.9**	**3087.2**	4
Echlin (8)	901.9	17	17	48.8	18	**7.3**	**16**	**0.8**	**8.7**	**668.3**	14
Equion (7)	58.4	26	188	2.8	NA	**1.2**	**48**	**2.0**	**20.4**	**2142.9**	NA
Hurco (10)	44.8	−3	13	−1.8	NA	**1.6**	**−49**	**3.6**	**NEG**	**4574.6**	−5
Modine Mfg. (3)	312.0	3	16	20.5	41	**6.3**	**−2**	**2.0**	**16.2**	**1765.3**	9
Raytech	113.5	1	−3	3.0	NA	**3.3**	**−15**	**2.9**	**71.6**	**2068.8**	NA
Sealed Power	665.8	7	17	28.5	5	**11.4**	**8**	**1.7**	**22.8**	**1622.8**	14
Smith (A. O.)	910.9	3	10	26.1	10	**8.1**	**−2**	**0.9**	**16.4**	**698.3**	4
Standard Products (6)	433.2	15	18	27.2	50	**4.9**	**10**	**1.1**	**10.0**	**857.5**	13
5 BUILDING MATERIALS											
INDUSTRY COMPOSITE	**13723.0**	**7**	**10**	**874.1**	**29**	**223.0**	**8**	**1.6**	**20.4**	**2072.7**	**5**
Ameron (11)	314.7	3	5	13.0	3	**3.6**	**−22**	**1.1**	**21.2**	**1285.7**	NA
Bird	184.4	−4	−8	0.4	NA	**1.2**	**−21**	**0.7**	**143.8**	**1004.1**	−15
De Soto	413.8	2	− 7	3.9	−26	**22.1**	**7**	**5.4**	**287.2**	**9995.5**	4
Guardsman Chemicals	97.8	2	9	3.9	42	**3.8**	**2**	**3.9**	**51.7**	**4952.3**	1
Lafarge	963.8	2	2	26.0	NA	**4.9**	**4**	**0.5**	**8.4**	**844.8**	−1
Lilly Industrial Coatings (11)	142.6	−2	9	8.5	18	**8.0**	**3**	**5.6**	**47.9**	**6795.2**	7
Manville	1920.3	2	4	81.2	NA	**35.8**	**13**	**1.9**	**25.9**	**1845.4**	NA
Moore (Benjamin)	352.5	10	12	25.5	18	**4.4**	**16**	**1.2**	**8.3**	**2424.4**	NA
Owens-Corning Fiberglas	3644.4	10	11	15.6	−8	**63.0**	**5**	**1.7**	**229.7**	**2626.9**	4
Pratt & Lambert	193.9	5	8	8.2	15	**3.8**	**8**	**2.0**	**25.5**	**2365.4**	5
Preway	112.8	−13	38	−12.3	NA	**1.1**	**−28**	**1.0**	**NEG**	**1066.0**	17
Sherwin-Williams	1552.9	2	4	96.0	26	**12.3**	**11**	**0.8**	**7.1**	**896.7**	−1
Sikes (2)	87.7	10	20	4.3	39	**1.0**	**60**	**1.1**	**12.2**	**891.8**	13
Stanadyne	492.8	2	10	21.1	12	**11.6**	**−2**	**2.4**	**27.7**	**2327.4**	3
Trus Joist	179.9	36	26	8.4	11	**2.6**	**40**	**1.5**	**16.7**	**1261.2**	20
USG	2723.7	17	26	255.4	65	**28.7**	**30**	**1.1**	**5.8**	**1322.0**	14
Valspar (10)	345.2	−1	27	14.8	17	**14.9**	**−4**	**4.3**	**55.7**	**7015.6**	19
6 CHEMICALS											
INDUSTRY COMPOSITE	**89797.0**	**0**	**2**	**4247.5**	**8**	**3662.2**	**6**	**4.1**	**48.6**	**6092.7**	**−1**
Air Products & Chemicals (9)	1982.1	8	6	4.7	−44	**61.1**	**20**	**3.1**	**805.0**	**NA**	NA
American Cyanamid	3815.9	8	5	202.5	7	**278.3**	**11**	**7.3**	**96.9**	**6075.6**	−4
Betz Laboratories	344.4	8	8	35.5	4	**13.1**	**9**	**3.8**	**19.6**	**4928.3**	4
Crompton & Knowles	213.2	9	6	8.9	21	**4.4**	**−4**	**2.1**	**27.3**	**3359.0**	NA
Detrex	94.2	7	8	2.5	−6	**2.6**	**60**	**2.8**	**55.5**	**3543.1**	9
Dexter	650.1	3	5	33.6	6	**27.6**	**7**	**4.2**	**48.8**	**5015.1**	0
Dow Chemical	11113.0	6	2	741.0	5	**605.0**	**11**	**5.4**	**48.9**	**11804.9**	−2
Du Pont	27148.0	−8	−1	1538.0	11	**1156.0**	**1**	**4.3**	**38.7**	**8183.0**	−4
Ecolab (6)	812.9	12	8	43.7	8	**10.9**	**53**	**1.3**	**15.0**	**1479.8**	2
Engelhard	2289.5	1	3	53.3	−9	**26.0**	**13**	**1.1**	**36.5**	**3788.1**	−1
Essex Chemical	205.6	8	11	8.8	7	**6.6**	**58**	**3.2**	**45.6**	**6562.4**	NA
Ethyl	1579.3	2	−2	177.7	15	**47.1**	**1**	**3.0**	**16.2**	**4481.4**	−8
Ferro	725.2	11	5	24.1	10	**11.7**	**8**	**1.6**	**26.0**	**1490.8**	−2
First Mississippi (6)	268.9	−2	7	−28.1	NA	**5.2**	**63**	**1.9**	**NEG**	**7809.1**	NA
Fuller (H. B.) (11)	528.5	15	12	18.9	15	**10.6**	**12**	**2.0**	**31.3**	**2356.9**	3
GAF	753.8	3	4	80.7	60	**11.4**	**10**	**1.5**	**9.1**	**2682.4**	0
Grace (W. R.)	3725.7	5	1	−375.4	NA	**94.2**	**5**	**2.5**	**NEG**	**2275.4**	NA
Great American Management (7)	499.2	105	65	−3.7	NA	**1.7**	**183**	**0.3**	**79.5**	**331.4**	NA
Great Lakes Chemical	300.3	8	14	26.8	12	**13.2**	**9**	**4.4**	**30.3**	**5992.3**	12
Grow Group (6)	366.2	33	14	10.1	17	**5.9**	**−11**	**1.6**	**29.5**	**1607.7**	NA
Hercules	2615.1	1	0	226.7	15	**71.1**	**−7**	**2.7**	**23.1**	**2532.1**	1
HIMONT (10)	980.9	8	NA	97.3	NA	**16.0**	**14**	**1.6**	**9.0**	**5713.9**	NA
International Minerals & Chemical (6)	1177.7	−7	1	−79.6	NA	**33.2**	**44**	**2.8**	**NEG**	**2388.5**	11
Koppers	1396.4	0	5	63.2	NA	**16.7**	**3**	**1.2**	**16.4**	**1530.2**	−11
Lawter International	103.5	7	6	12.9	5	**2.3**	**9**	**2.2**	**11.1**	**6248.6**	4
LeaRonal (2)	105.0	−20	−10	6.0	−3	**1.7**	**7**	**1.6**	**16.4**	**5076.9**	7
Liquid Air	570.6	5	7	34.7	8	**5.7**	**5**	**1.0**	**10.1**	**1292.9**	3
Loctite (6)	266.8	15	5	23.2	10	**10.1**	**15**	**3.8**	**29.5**	**3772.9**	2
Lubrizol	985.2	8	5	78.2	10	**51.2**	**18**	**5.2**	**39.8**	**10667.0**	4
MacDermid (3)	86.3	−9	12	3.8	7	**4.2**	**20**	**4.9**	**60.1**	**6483.1**	8
Monsanto	6879.0	2	2	433.0	7	**523.0**	**11**	**7.6**	**82.2**	**10115.5**	1
Morton Thiokol (6)	1949.9	6	34	132.9	39	**37.7**	**12**	**1.9**	**16.7**	**2106.1**	27

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R&D SCOREBOARD

COMPANY	SALES			PROFITS		R&D EXPENSES				EMPLOYMENT	
	1986 MILLIONS OF DOLLARS	PERCENT CHANGE FROM 1985	PERCENT ANNUAL CHANGE (1982-86)	1986 MILLIONS OF DOLLARS	PERCENT ANNUAL CHANGE (1982-86)	1986 MILLIONS OF DOLLARS	PERCENT CHANGE FROM 1985	PERCENT OF SALES	PERCENT OF PRETAX PROFITS	R&D DOLLARS PER EMPLOYEE	ANNUAL CHANGE EMPLOYMENT (1982-86)
Nalco Chemical	736.1	8	5	63.7	2	33.2	4	4.5	29.2	6825.8	2
Oil Dri Corp. of America (7)	52.8	14	12	4.6	48	0.6	18	1.2	9.9	1382.2	6
Olin	1707.3	-3	2	75.2	17	56.0	5	3.3	48.7	4244.1	-2
Pennwalt	1107.6	8	6	51.9	3	45.0	14	4.1	64.4	4892.2	NA
Petrolite (10)	280.0	-9	-1	17.5	-10	12.1	-2	4.3	43.0	5642.3	NA
Products Research & Chemical (9)	92.0	10	12	7.3	21	5.3	16	5.7	41.3	7198.6	NA
Quaker Chemical	128.1	4	8	8.5	16	7.0	24	5.5	49.3	7565.1	0
Reichhold Chemicals	765.6	-7	0	15.9	26	14.0	11	1.8	47.8	3537.1	-2
Rohm & Haas	2067.0	[illegible]	3	138.0	10	132.8	8	6.4	60.6	11010.0	[illegible]
Sequa	371.4	14	10	26.1	22	11.3	38	3.0	39.3	718.8	NA
Stepan	259.8	10	6	7.5	6	9.5	15	3.6	67.4	9986.3	1
Union Carbide	6343.0	-1	0	130.0	NA	148.0	-16	2.3	65.5	2942.8	-4
Witco	1355.0	-6	1	65.2	18	21.9	4	1.6	20.2	2734.4	0
7 CONGLOMERATES											
INDUSTRY COMPOSITE	**52113.6**	**11**	**15**	**-843.7**	**10**	**1354.2**	**12**	**2.6**	**140.5**	**2187.1**	**13**
Allied-Signal	11794.0	29	20	605.0	19	459.0	34	3.9	50.6	3345.5	34
Colt Industries	1616.3	2	7	89.3	5	31.6	18	2.0	20.5	1716.6	0
Figgie International	919.8	14	9	42.4	13	15.7	11	1.7	19.3	965.7	8
ITT	7595.5	16	NA	527.9	NA	208.0	-12	2.7	18.2	1691.1	NA
Kidde	2356.2	9	6	52.2	3	21.3	33	0.9	23.3	560.5	NA
LTV	7271.4	-11	15	-3251.6	NA	19.5	-13	0.3	NEG	403.7	14
Rockwell International (9)	12295.7	8	15	611.2	18	407.5	11	3.3	38.5	3362.4	6
Teledyne	3241.4	0	3	238.3	3	84.6	-11	2.6	24.9	1888.4	1
Textron	5023.3	24	29	241.6	42	107.0	26	2.1	24.1	1486.1	15
8 CONTAINERS											
INDUSTRY COMPOSITE	**1191.7**	**-2**	**6**	**65.4**	**17**	**19.4**	**3**	**1.6**	**15.7**	**1878.6**	**NA**
Ball	1070.3	-3	6	58.9	14	17.0	2	1.6	15.4	1888.9	-1
Sealright	121.4	8	9	6.5	52	2.4	9	2.0	18.0	1809.1	NA
9 DRUGS ETHICAL, PROPRIETARY, MEDICAL & HOSPITAL SUPPLIES											
INDUSTRY COMPOSITE	**60549.5**	**19**	**8**	**6311.6**	**9**	**4721.0**	**17**	**7.8**	**48.4**	**8171.9**	**1**
A. L. Laboratories	121.7	26	54	5.5	99	3.1	33	2.5	28.0	2904.8	1
Abbott Laboratories	3807.8	13	9	540.5	17	284.9	18	7.5	34.8	7968.1	2
ALZA	51.6	27	26	9.0	30	19.4	34	37.6	106.5	NA	NA
American Home Products	4926.5	5	5	778.8	10	227.1	5	4.6	18.2	5221.4	-2
Bard (C. R.)	548.0	18	12	51.2	16	19.2	25	3.5	22.9	2666.7	4
Baxter Travenol Laboratories	5543.0	136	30	181.0	-5	203.0	62	3.7	78.1	3295.5	22
Becton, Dickinson (9)	1311.8	15	4	111.9	18	70.6	18	5.4	40.9	3657.4	-3
Biocraft Laboratories (3)	42.9	26	29	6.2	105	1.8	130	4.3	15.8	7973.9	NA
Bolar Pharmaceutical	55.2	44	29	10.0	27	4.6	15	8.3	25.0	18300.0	16
Bristol-Myers	4835.9	9	7	589.5	14	311.1	14	6.4	33.4	8914.0	NA
Carter-Wallace (7)	400.2	15	11	27.6	21	25.7	12	6.4	56.0	6618.3	4
Cetus (6)	39.6	-13	31	1.1	-22	6.0	-19	15.1	480.4	9501.6	8
Cooper Development (10)	174.2	104	53	-61.7	NA	17.7	74	10.2	NEG	3884.0	64
E-Z-EM (5)	47.5	22	13	6.9	28	1.7	39	3.6	16.7	2730.2	11
Forest Laboratories (3)	39.7	49	20	6.8	31	3.1	5	7.7	37.1	6073.6	NA
Genentech	127.3	56	44	-352.2	NA	32.2	39	25.3	NEG	27568.5	26
ICN Biomedicals (11)	41.1	155	50	3.1	43	0.8	10	1.9	13.5	1773.5	NA
ICN Pharmaceuticals (11)	102.8	64	28	9.4	34	6.2	32	6.0	31.3	3845.0	28
Johnson & Johnson	7002.9	9	5	329.5	-7	521.3	11	7.4	133.4	6761.3	-1
Life Technologies	98.3	17	19	3.7	17	7.4	25	7.6	109.0	6281.7	NA
Lilly (Eli)	3720.4	14	5	558.2	8	427.0	15	11.5	48.7	14673.5	-1
LyphoMed	129.3	89	90	15.7	96	4.8	97	3.7	16.7	3671.5	69
Marion Laboratories (6)	399.3	35	27	55.0	58	52.8	24	13.2	55.4	20574.6	11
Merck	4128.9	16	7	675.7	12	479.8	13	11.6	43.7	15628.7	-1
Mylan Laboratories (3)	80.8	51	27	20.7	60	4.1	34	5.0	10.8	13100.0	7
Par Pharmaceutical (9)	39.4	85	53	4.6	69	2.8	52	7.2	33.9	5438.5	NA
Pfizer	4476.0	11	6	660.0	17	335.5	17	7.5	34.8	8387.5	-1
Robins (A. H.)	789.9	12	13	81.8	12	51.8	-1	6.6	33.5	8100.6	3
Rorer Group	844.6	150	26	3.5	-33	69.7	289	8.3	465.4	9235.8	NA
Scherer (R. P.) (3)	185.8	11	2	-10.6	NA	4.9	31	2.7	187.0	1993.9	5
Schering-Plough	2398.7	15	7	265.8	7	212.1	12	8.8	56.7	9025.5	-3
SmithKline Beckman	3745.4	15	9	521.1	3	376.9	22	10.1	52.2	11168.4	3
Squibb	1784.6	27	11	263.6	20	163.0	17	9.1	43.2	9639.1	[illegible]
Sterling Drug	1990.4	14	4	171.5	8	102.9	21	5.2	34.3	4654.4	-3
Syncor International (5)	93.6	151	43	1.4	NA	1.2	-9	1.3	58.4	928.4	NA
Syntex (7)	980.0	15	8	207.6	10	143.0	17	14.6	58.9	15546.1	1
Upjohn	2291.4	14	9	252.6	12	314.1	11	13.7	87.7	15174.6	2
Warner-Lambert	3102.9	-3	-1	309.5	15	202.3	-3	6.5	45.4	6524.3	-7
Zenith Laboratories	50.4	-37	22	-4.1	NA	5.4	90	10.6	NEG	11654.3	17

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Appendix I

EXHIBIT 1

THE SECRETARY OF
HEALTH AND HUMAN SERVICES,
Washington, DC, March 10, 1986.

Hon. STROM THURMOND,
Chairman, Committee on the Judiciary, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: There is pending before the Committee, S. 1093, a bill "To amend the patent law to restore the term of the patent in the case of certain products for the time of the regulatory review period [illegible] the marketing of the product claimed in the patent." We take this opportunity to inform you of our views on that bill. We understand that S. 1093 is scheduled for markup on March 11, 1986 before the Subcommittee on Patents, Copyrights and Trademarks.

Our views focus on S. 1093 as it would affect veterinary drugs, which are regulated by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic (FDC) Act. S. 1093 would authorize the restoration of patent time lost due to Federal premarket requirements for veterinary drugs, pesticides, and agricultural chemicals.

In summary, we support patent restoration for veterinary drugs, but urge the Committee to add an additional provision that would enable manufacturers to obtain Federal premarket approval to market generic versions of these drugs without having to duplicate the potentially costly and time-consuming safety and effectiveness studies that are required of pioneer manufacturers. Without such a provision, there would appear to be no need for patent restoration since the current Federal requirement for duplicative testing would continue to serve as an effective economic barrier to competition even after the expiration of patents that would be restored by this legislation.

The Department of Health and Human Services traditionally has supported patent restoration for the products that require the premarket approval of FDA. These products often entail high development costs, the risk of failure and small potential markets. In addition, innovators typically lose years of patent exclusivity because of testing requirements and regulatory review. We are mindful of the paradox that the careful and time-consuming scientific review needed to confirm safety and effectiveness may be reducing initiatives to develop new veterinary drugs. Streamlining the regulatory process will help. However, the FDA premarket approval system must continue to be thorough enough to assure safety and efficacy even if that means living with a process that takes longer than we would ideally prefer. We want to encourage innovation, but not at the expense of safety. Consequently, we support patent extension for veterinary drugs as a means of encouraging innovative research.

Patent restoration would have little meaning, however, if Federal regulatory barriers had the effect of preventing the marketing of virtually identical generic products after patents expire. Such a situation existed for human drugs until 1984, when the Congress enacted legislation that both extended patents associated with human drugs and removed regulatory barriers that effectively prevented the development of many generic human drugs. The situation still exists, however, for veterinary drugs.

Consequently, in addition to patent extension, we strongly support the enactement of an explicit statutory authority that would allow a manufacturer to market a generic version of a veterinary drug without having to duplicate the time-consuming and costly studies that are necessary to demonstrate that the original version of the drug is safe and effective. The generic manufacturer only would have to demonstrate in an "abbreviated" application for marketing approval to FDA that it is capable of manufacturing an equivalent product.

FDA presently allows abbreviated applications for generic versions of veterinary drugs that were approved before 1962, the year in which Congress amended the FDC Act to require that both human and veterinary drugs be shown to be effective as well as safe. A similar procedure has not been established for post 1962 veterinary drugs. As a consequence, the duplicative testing for safety and effectiveness that generic manufacturers must conduct for post 1962 drugs [illegible] an effect [illegible] barrier to their development. In this respect, the Federal drug approval process unwittingly serves as a quasi-patent whose term never expires.

We have concluded, therefore, that both patent restoration and an abbreviated approval procedure ought to be included in the same legislation so that they may be considered and, hopefully, enacted together. We continue to belive that it is good public policy to link the two concepts in order to foster research for new products and at the same time encourage competition and lower prices. In our view, it would be unfair to consumers as well as to the industry as a whole if one were enacted but not the other or if a substantial time lag occured between the enactment of both. We would be pleased to work with the Committee to add an abbreviated application provision to S. 1093.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

OTIS BOWEN,
Secretary.

PREPARED STATEMENT OF JIMMY WHATLEY, DIRECTOR, CORPORATE RESEARCH & DEVELOPMENT, GRIFFIN CORP., VALDOSTA, GA

Gentlemen, my name is Jimmy Whatley. I am the Director of Corporate Research and Development at Griffin Corporation in Valdosta, Georgia. Our sales are substantially under $75 million per year. I have senior management responsibility for our registration matters and our data compensation activities. I appreciate the opportunity to appear here this afternoon, and would like to take this opportunity to build on what you've heard from Mr. Stickle and describe to you some of the practical elements of the current arbitration system which I believe merit your attention.

First of all, the system is nowhere near as simple and cost effective as you might think. First and foremost among the factors which have made it complex is the lack of an explicit, clear compensation standard in the statute. Because of this, arbitration hearings have been expanded to include not only an evaluation of competing estimates of the cost of producing certain data, but also a wide variety of testimony on economic theories related to how compensation might be measured.

Let me try to be concrete about this. In one pending arbitration, we have had about two weeks direct testimony on such matters as the original registrant's efforts to develop the product -- although they admittedly had sixteen years patent protection for it -- and expect to have another week or more of direct testimony from various economists as to the impact of data compensation on innovation, alternative royalty schemes, and the like. Now this will just be the claimant's testimony. In order that the record can be complete, we and our co-respondent have been forced to retain our own experts both to respond to the claimant's arguments and provide a more balanced view. In all, I would guess that the total amount spent on these expert economists and consultants in this case will exceed $100,000, and that we will spend another $100,000 or more on lawyers just in preparing and dealing with this portion of the arbitration. And, as you will recall, we also have to pay the arbitrators to listen to these issues.

In large part this expenditure has been incurred simply because, given the current ambiguous situation, the arbitrators have not been prepared to rule prior to hearing on the applicability of the royalty theory being advanced in that case. This, of course, evidences the insidious impact of the PPG decision described by Mr. Stickle.

But there are other, less obvious, practical impacts of the ambiguities in the statute. For example, notwithstanding FIFRA's clear cutoff on compensation for any data submitted prior to 1970, we now are facing the argument that the original submitter's recitation of that data after 1970, in support of subsequent registration activities, is enough to trigger a compensation obligation. This argument has resulted in a further enormous expense in the arbitration process, as we are forced to pay lawyers, experts and arbitrators even more to sit through and respond to hours and hours of testimony regarding this data.

Arguments also are being made in our current proceeding that compensation is being required for so-called "efficacy data" -- that is, data relating to the effectiveness of pesticides. Prior to our obtaining our registrations, EPA had waived any need for us to provide such data. Nonetheless, we now face a clever legal theory as to why this data is compensable, and we are being forced to respond to that theory, to sit through the hours of testimony, and to pay the lawyers, experts and arbitrators charges as to those activities.

Another tactic we are facing is the effort to read Section 3(c)(2)(B) entirely out of the statute. Thus, it is being argued that data produced in response to a data call-in is not subject to cost-sharing with other existing registrants under Section 3(c)(2)(B), but rather is compensable under Section 3(c)(1)(D). Combined with the theory that Section 3(c)(1)(D) allows compensation for something more than cost, this argument would even more greatly exaggerate our obligations.

In short, the arbitration system is nowhere near as efficient as one would hope. If the Congress is to retain data compensation obligations, the most important step it could take would be to clearly establish, in express statutory terms, the standard of compensation. Another vital step would be to eliminate -- perhaps through express legislative history -- any ambiguity as to other matters such as those I've just outlined which currently allow the arbitration process to be abusively extended.

Now, in the real world I don't believe that even the clearest legislative history would totally resolve this matter. After all, where there are opportunities for companies to obtain millions of dollars in windfall awards, claimants' lawyers no doubt will be able to come up with new, creative legal theories which might somehow sweep into arbitration proceedings additional compensation claims. To deal with this, it seems to me that Congress should encourage the American Arbitration Association to revise its rules governing proceedings in one important respect. That is to encourage arbitrators to make early decisions on the legal principles controlling any arbitration proceeding.

Allow me again to be specific. In several arbitrations to date panels have been willing to make such preliminary decisions. For example, in the FMC v. Tricon arbitration, an early decision by the panel that Section 3(c)(2)(B) compensation need not necessarily be based on a per capita allocation provided the basis for a quick settlement. In another proceeding, an early decision on the question of who owned certain data rights provided the basis for settlement prior to any evidentiary hearing. In short, these preliminary decisions substantially narrowed the hearing process and would have lead to much quicker, and therefore less expensive, hearings had the cases gone forward.

In contrast, other panels have not entertained early motions to resolve the controlling legal principles. As a result, hearings have dragged on. While I stress I am not criticizing any particular panel -- I understand the difficulties arbitrators face -- I must also emphasize that hearing weeks are not inexpensive. By my estimate, with payments to three arbitrators, three law firms, and various expert witnesses, our current hearing is costing all parties together about $15,000 a day. And that's just for hearing time -- it doesn't include preparation, briefing, or any of the other costs that ultimately will be associated with this case. The case probably will ultimately cost all parties a total of $1.5 million.

We understand that the American Arbitration Association is currently considering how it might improve its rules and expedite these proceedings. We suggest that the Congress provide guidance to AAA, through the current FIFRA reauthorization process, that it is the Congress' desire that the arbitration rules should be revised to make FIFRA arbitration hearings as efficient and inexpensive as possible, without of course eliminating any due process protections which may be constitutionally required. This step, in combination with the others I have outlined above, would be a major benefit to all participants and especially to those smaller companies, such as Griffin, as to which the mere expense of an arbitration hearing is itself a major, and anti-competitive, deterrent to market entry.

I understand that time does not allow me to address these matters further today. I would be pleased, however, to answer any questions you may have.

PREPARED STATEMENT OF VIRGIL YOUNG, PRESIDENT, TENKOZ, INC.

Mr. Chairman, my name is Virgil Young. I am president of Tenkoz, Fort Valley, Georgia. Tenkoz is owned by seven formulator/distributor companies across the country from Yuma, Arizona to Severn, North Carolina. Tenkoz functions as a purchasing consultant for these small businesses who have a combined $300 million share of the ag chemical market. We employ some 650 people in some 20 states. Some of our companies are members of CPDA; others are members of NACA.

Mr. Chairman, I would like to comment on three areas: 1) data compensation, 2) the need to repeal the Bolar/Roche decision and 3) the need for generic registration.

Data Compensation:

I believe that it is possible to stimulate greater competition in the pesticide industry if we can make it easier for small businesses, formulators and distributors to enter the pesticide market. By changing the current "data compensation" provisions of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), we can achieve this goal.

When a human drug comes off patent, a generic manufacturer can enter the market simply by demonstrating to the FDA that it is capable of producing the same chemical compound. Not so when a pesticide comes off patent. Current law requires the would-be generic manufacturer to submit enormous amounts of health and safety data to EPA in order to get a registration to allow marketing. The generic producer can either (1) generate his own data, which takes five to seven years, or (2) he can purchase the right to cite the data previously submitted to EPA according to a complex, lengthy and costly procedure from the originator.

In that event, the generic manufacturer must offer to pay compensation to the holder of the data (product is patent free) so that EPA may refer to that data in their files in considering an application for registration by a generic manufacturer. Section 3 of FIFRA, however, set no clear standard for the compensation that must be paid. Using general accounting practices, the data producer can write off most of the cost of data development in the year the cost is incurred, thus leaving the public financially responsible for the cost of the data. With the general public actually paying the cost of the production of data, these data should be in the public domain, thereby allowing generic registration.

When a company decides to enter a pesticide market, after the expiration of the patent, it must be able to determine all of its potential costs in order to make a sound business decision. It can define (1) the manufacturing process, (2) raw material costs, (3) cost of plant construction, (4) general overhead, and

(5) potential market. While these items are sufficient in most businesses, there is one important element missing for a pesticide product: data compensation for the use of data submitted by another registrant to support the registration of your product.

On its face, FIFRA provides that, if a registrant relies on data submitted by another registrant, he must offer to pay compensation to the original data submitter. The statute does not provide a definition of "reasonable compensation." If the parties involved cannot reach an agreement, then either one may request that the matter be submitted to binding arbitration before the Federal Mediation and Conciliation Board, which is to determine "reasonable compensation."

Small businesses and generic manufacturers are reluctant to attempt to enter markets when their potential data compensation costs will exceed their profits for many years.

As a result of a recent arbitration decision, it has become difficult for any generic manufacturer to enter the market on a timely basis and at a reasonable cost. The arbitration award required the generic manufacturer to pay compensation to the original data submitter in the amount of over five times the cost of producing the data for the privilege of citing the data in its registration application. The loser in this case are our farmers and ranchers who continue to pay higher prices for their pesticides.

It would be very difficult for a small company to decide to enter a market previously held by a major producer. The cost of such an arbitration award under the law would be out of reach of a small businessman. If he were successful in obtaining entry into a market, he could still be faced with future development of several million dollars worth of data when the registration standard for the product was issued, and when he was required to reregister his product.

We believe that a decision such as the Stauffer/PPG decision is totally outside the intent of Congress when it passed the requirements for reasonable compensation in 1972, or when the statute was amended in 1975 and 1978. We believe the intent of this section was to allow a company which relied upon data submitted to the Agency by another registrant to share in the cost of development of that data and not to reward the original registrant for being the first to register the pesticide product. We contend that such reward is the purpose of the patent laws and not FIFRA.

The Need to Repeal the Bolar/Roche Decision:

Current patent law allows the recipient of a pesticide patent an exclusive life of 17 years. Basic supplier companies have requested legislative changes to this law by asking that up to five additional years of patent life be added to the pesticide product. The intent of the legislation is to restore lost patent life resulting from the lengthy regulatory review period needed to obtain EPA approval. While a product is being reviewed, it cannot be marketed.

In addition to the anti-competitive nature of the present system of determining data compensation, a recent decision by the United States Court of Appeals has brought into question the practice of developing data necessary to support the registration of an identical pesticide product prior to the expiration of a patent.

On April 23, 1984, the United States Court of Appeals for the Federal Circuit handed down a decision in Roche Products, Inc. vs. Bolar Pharmaceutical Co., Inc. ruling that the use of a patented product by a second party to develop data for the purpose of obtaining an early market entry following the expiration of a patent was a violation of the "use" provisions of the law. The Court held that, while there was an exemption for the use of a product for scientific purposes, the exemption did not apply when the information gained was for commercial purposes. This decision prohibits the manufacturer of a generic pesticide from developing any data which would be necessary for the registration of one product prior to the expiration of its patent.

This court decision effectively adds a period of up to seven years to the term of a patent, in addition to the proposed five-year extension, totaling a patent life of 29 years if the bill should become law. This is shown in the following scenario:

....Regular patent, 17 years....17 years
....With patent term extension....22 years
....Bolar/Roche cost of time 5-7 years....29 years

In section 202 of the Drug Price Competition and Patent Term Restoration Act of 1984, provisions were included to overrule the Bolar/Roche decision. Essentially, those provisions stated that it would not be an act of infringement to make, use or sell a patented invention solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use or sale of drugs.

If a product is to receive patent extension, as originally proposed by H.R. 2482 and S. 2792 (99th Congress), or as proposed in H.R. 1345, introduced by Congressmen Frederick Boucher and Michael DeWine, there should be a full repeal of the Bolar/Roche decision. These legislative vehicles do not, however, contain a full repeal, but only a limited repeal, for just two years. Such a limited repeal provides little benefit to generic manufacturers, especially if the testing and EPA review take five to seven years, leaving us with a three to five year deficiency. In addition, the Bolar/Roche decision does not allow the generic manufacturer to submit his test results for EPA review prior to the expiration of the patent. Congress wisely created the generic pharmaceutical industry following patent term restoration and we feel that such a move within the pesticide industry would benefit all users.

We at CPDA believe that a generic manufacturer in the pesticide industry should be on equal footing with drug manufacturers and do the testing and file an application for registration before the expiration of a patent, as long as there is a prohibition against marketing before the patent expires.

These de facto circumstances created by Bolar/Roche clearly prohibit market entry, deny small businesses access to the market place and deprive farmers and consumers of lower priced pesticides.

Generic Registration:

We support H.R. 2569, the Pesticide Price Competition Act of

1987, introduced by Congressmen Charles Hatcher and Richard Ray. This legislation is patterned after the generic drug legislation that was enacted in 1984.

We think it is unfair to us and the farmer when we are kept out of the market after patent expiration. Paying for data after the patent expires is unfair to us. If one can prove to the EPA that his technical chemical is the same chemistry as the one registered and supported with data, it should be registered.

Let's take a moment to consider data cost. The data cost was paid for by the patent holder of the chemical, which lowered his tax obligation on the profits made. So the tax payers have paid for that. Pricing of the product has included profits to offset all the research and development expenses. Who is the consumer in this case? None other than our farmers. In the early life of the product, the farmer pays the data cost. When the patent has expired, they want any would-be competitor to pay it again. If they do pay it, who will pay them back for the expense? You guessed it--the farmer! Why should he pay again? In fact, the patent holders want the data compensation based on a multiple of their actual cost. They do not deserve to collect for the data two or three times while our farmers struggle. They do not really want the money for the data. They want to see businesses like ours and others give up the ship. And that is what will happen without drastic changes.

The small businessman can provide a quality product to the farmer at a lower cost. Large companies know and fear this fact. Dollars for the data cost is really not what they want. A protected market position that provides continuing high profit opportunities at the expense of the farmer is what they want.

As contained in H.R. 2569, generic registration would assist small business, formulators and manufacturers in entering the marketplace after the expiration of the patent, breathe a new competitive spirit into the pesticide industry and put us on par with the generic drug industry.

But, most importantly, Mr. Chairman, it would lower pesticide costs for our farmers, ranchers, users and consumers.

I thank you for the opportunity to appear here today and would be happy to answer any questions the subcommittee has.

ATTACHMENT TO TESTIMONY OF ROBERT D. SHOCKEY

APPENDIX I

PESTICIDES AND THE COST OF PRODUCTION: POTENTIAL FARM SAVINGS OF H.R. 2569/S. 746

Crop*	1985 cost of chemicals per acre***	1985 chemical percentage of cash variable expenses	Savings per acre if prices drop 20 % due to generic competition
Corn	$17.58	8.6%	$3.52
Sorghum	8.52	13.4%	1.70
Barley	5.43	10.4%	1.09
Oats	1.11	.3%	.22
Wheat-all	2.93	5.9%	.59
Spring wheat	5.09	12.5%	1.02
Durum wheat	5.35	14.2%	1.07
White wheat	9.58	12.9%	1.92
Winter wheat	1.50	3.3%	.30
Rice	26.88	10.8%	5.38
Soybeans	17.47	32.3%	3.50
Sunflower	13.30	27.3%	2.66
Peanuts-all	79.63	29.3%	15.93
" southeast	94.58	33.0%	18.92
" VA & NC	88.76	28.7%	17.75
Flax	4.15	13.6%	.83
Cotton-all	45.18	20.5%	9.04
" Delta	72.27	32.3%	14.45
" southeast	96.04	35.7%	19.21
Sugar beets	44.57	15.3%	8.91
" TX and NM	101.13	22.9%	20.21
Sugar cane	56.44	7.5%	11.29
" Hawaii	125.64	4.8%	25.13
Tobacco**			
" burley	70.08	3.6%	14.02
" flue-cured	94.44	4.6%	18.89

* *Economic Indicators of the Farm Sector, Costs of Production, 1985* (United States Department of Agriculture, Economic Research Service, ECIFS 5-1.

** Annette Clausen, Economic Research Service, USDA.

*** Chemical category does *not* include fertilizers.

100th CONGRESS
1st Session

H. R. 2569

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to permit applicants to file abbreviated applications for registration of pesticides or new uses of pesticides under certain circumstances, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

June 2, 1987

Mr. Hatcher (for himself and Mr. Ray) introduced the following bill; which was referred to the Committee on Agriculture

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A BILL

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to permit applicants to file abbreviated applications for registration of pesticides or new uses of pesticides under certain circumstances, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Pesticide Price Competition Act".

SEC. 2. ABBREVIATED APPLICATIONS FOR REGISTRATION OF PESTICIDES AND NEW USES OF PESTICIDES.

(a) IN GENERAL.—Section 3(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a(c)) is amended by adding at the end thereof the following new paragraph:

"(9) ABBREVIATED APPLICATIONS.—

"(A) An applicant may file with the Administrator an abbreviated application for the registration of a pesticide, or for an application for an amendment adding a new use to the registration of a pesticide, in accordance with this paragraph.

"(B) The application shall contain—

"(i) information to demonstrate that—

"(I) the pesticide is identical or substantially similar chemically to a pesticide previously registered under this Act;

"(II) the conditions of use recommended in the labeling proposed for the pesticide have been approved for the previously registered pesticide; and

"(III) the labeling proposed for the pesticide is the same as the labeling approved for the previously registered pesticide, except for differences approved by the Administrator under other provisions of this Act; and

"(ii) a certification that to the best of the knowledge of the applicant no data that has been previously submitted to the Administrator for the previously registered pesticide is entitled to exclusive use under paragraph (1)(D)(i).

"(C) Notwithstanding any other provision of law, paragraphs (1)(D) (other than clause (i)), (2)(B)(v), and (2)(D) shall not apply to an application filed under this paragraph.

"(D) Nothing in this paragraph shall be construed to supersede part II or III of title 35, United States Code.".

(b) TABLE OF CONTENTS.—Section 1(b) of such Act (7 U.S.C. prec. 121) is amended by inserting between the items relating to sections 3(c)(8) and 3(d) the following new item:

"(9) Abbreviated applications.".

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